STRONGBRIDGE BIOPHARMA plc

Directors' Report and Consolidated Financial Statements

For the Financial Year Ended December 31, 2016

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COMPANY INFORMATION

DIRECTORS	Marten Steen (Swedish National) Hilde Steineger (Norwegian National) John Johnson (US National) Richard Kollender (US National) Matthew Pauls (US National) Garheng Kong (US National) Jeffrey Sherman (US National, appointed October 1, 2016)
COMPANY SECRETARY	Stephen Long
REGISTRATION NUMBER	562659
REGISTERED OFFICE	Arthur Cox Building Ten Earlsfort Terrace Dublin 2 D02 T380 Ireland
ADMINISTRATOR	TMF Administration Services Limited 3rd Floor, Kilmore House Park Lane, Spencer Dock Dublin 1 Ireland
BANKERS	Silicon Valley Bank 3003 Tasman Drive Santa Clara CA 95054 United States of America Bank of America Bank of America Corporate Center 100 North Tryon Street Charlotte NC 28255 United States of America
SOLICITORS	Arthur Cox Ten Earlsfort Terrace Dublin 2 D02 T380 Ireland

COMPANY INFORMATION (CONTINUED)

INDEPENDENT AUDITOR	Ernst & Young Chartered Accountants Harcourt Centre Dublin 2 Ireland

DIRECTORS' REPORT
FOR THE YEAR ENDED DECEMBER 31, 2016

The directors present their annual report and audited consolidated financial statements of Strongbridge Biopharma plc (the “Company”) for the year ended December 31, 2016.

The directors have elected to prepare the consolidated financial statements in accordance with Section 279 of Part 6 of the Companies Act 2014, which provides that a true and fair view of the state of affairs and profit or loss may be given by preparing the financial statements in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP), as defined in Section 279(1) of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of that part of the Companies Act 2014.

PRINCIPAL ACTIVITIES, BUSINESS REVIEW

The Company is a public limited company, which was incorporated on May 26, 2015, in accordance with the laws of Ireland with registration number 562659.

The Company is a biopharmaceutical entity focused on the development, in-licensing, acquisition and eventual commercialisation of multiple complementary products and product candidates within franchises that target rare diseases.

On September 8, 2015, Cortendo AB became a subsidiary of the Company with 99.582% of its shares being owned by the Company. In September 2016, the Company acquired the non-controlling interest in Cortendo AB, after which Cortendo AB became a wholly-owned subsidiary of Strongbridge PLC. Total consideration paid per share was $13.66 resulting in a payment of $1.4 million.

On December 22, 2016, the Company raised $35 million in aggregate proceeds in a private placement (the "2016 Private Placement"). According to the terms of the Securities Purchase Agreement, dated December 22, 2016, we issued and sold 14,000,000 ordinary shares at a purchase price of $2.50 per ordinary share, as well as warrants to purchase 7,000,000 ordinary shares (the "Investor Warrants"), to the investors (the "2016 Investors"). The Investor Warrants are exercisable at a price of $2.50 per share beginning on June 28, 2017 and expire in five years from June 28, 2017. In connection with the 2016 Private Placement, we entered into a registration rights agreement with the 2016 Investors, pursuant to which we agreed to file the registration statement for the purpose of registering for resale (i) the ordinary shares purchased by the 2016 Investors in the 2016 Private Placement, (ii) the ordinary shares exercisable upon exercise of the Investor Warrants acquired by the 2016 Investors in the 2016 Private Placement, and (iii) any other ordinary shares held by a 2016 Investor that beneficially owned at least 1,000,000 ordinary shares following the closing of the 2016 Private Placement that qualified as "Registrable Securities" as defined therein (the "Existing Shares").

On December 28, 2016, we entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Horizon Technology Finance Corporation ("Horizon"). The Loan Agreement provided for a $40 million credit facility, of which $20 million was borrowed initially. Under the Loan Agreement, we have access to two additional tranches of $10 million each, which would be available to us subject to the achievement of certain specified milestones. The borrowings pursuant to the Loan Agreement mature after 48 months. The Loan Agreement provides for interest-only payments initially for the first 18 months of the loan followed by an amortization period of 30 months, provides for a final payment fee equal to 8% of the amount borrowed, and bears interest at a rate equal to the sum of 8.22% plus the greater of 0.53% or the 30-day US LIBOR rate. The credit facility provides that if we satisfy certain milestones and borrow the final $10 million tranche, the interest-only period would be extended by an additional six months and the amortization period would be 24 months. We have granted a security interest in substantially all of our existing assets and assets acquired by us in the future, including intellectual property. The Loan Agreement contains facility and prepayment fees, and customary affirmative and negative covenants, and events of default.

Upon the execution of the Loan Agreement, we issued warrants to each of Oxford and Horizon (the "Lenders") to purchase an aggregate of 428,571 ordinary shares at an exercise price equal to $2.45 per share (the "Lender Warrants"). The Lender Warrants are immediately exercisable and expire after ten years. The Lender Warrants issued to the Lenders include a provision requiring us to file the registration statement to provide for the public resale of the ordinary shares to be issued upon exercise of the Lender Warrants.

On March 31, 2017 we entered into an amendment to the Loan Agreement that was made effective as of January 27, 2017 and provided for an extension to the dates by which the Company’s Swedish subsidiary was required to enter into security documents granting security interests on certain of its assets in favor of Oxford, as collateral agent for the Lender, and to increase the amount of debt the Company can incur under, and the amount of cash collateral it can provide for purposes of, its corporate credit card program from $100,000 to $250,000. In connection with the amendment, the Company paid $150,000 to the Lenders.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL ACTIVITIES, BUSINESS REVIEW (CONTINUED)

In December 2016, we initiated our rare neuromusculare franchise by acquiring the U.S. marketing rights to KEVEYIS® (dichlorphenamide) from Taro Pharmaceuticals U.S.A., Inc., the U.S. subsidiary of Taro Pharmaceutical Industries Ltd. (Taro). KEVEYIS is the first and only therapy approved in the United States to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis (PPP), a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis.

Under the terms of the Asset Purchase Agreement, we paid Taro an upfront payment of $1 million in December 2016 and will pay an additional $7.5 million to Taro by March 22, 2017, as well as an aggregate of $7.5 million in potential milestones upon the achievement of certain product sales targets. Taro has agreed to continue to manufacture Keveyis for us under an exclusive supply agreement through the orphan exclusivity period. We are obligated to purchase certain annual minimum amounts of product totalling approximately $29 million over a six-year period from Taro.

SUBSIDIARIES

Refer to note 20 to the consolidated financial statements for information regarding the Company's subsidiaries.

PRINCIPAL RISKS AND UNCERTAINTIES

The Company's business is subject to a number of risks. These risks include, but are not limited to, the following:

Risks Related to Our Limited Operating History

We have a limited operating history on which to assess our business, have incurred significant losses over the last several years, and anticipate that we will continue to incur losses until we successfully commercialize Keveyis and one or more of our product candidates.

Until we acquired the U.S. marketing rights to Keveyis®, in December 2016, we were a development-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain regulatory approval or manufacture and commercialize a product candidate. Consequently, we have no meaningful commercial operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Since inception, we have incurred significant operating losses. Our net loss was $50.3 million and $43.6 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016 we had an accumulated deficit of $131.1 million. We have devoted substantially all of our financial resources to identifying, in-licensing, acquiring and developing our product candidates, including conducting clinical trials as well as providing general and administrative support for these operations.

To date, we have financed our operations primarily through private placements of equity securities and the proceeds from our initial public offering of ordinary shares in the United States in October 2015. The amount of our future net losses will depend, in part, on whether we successfully commercialize Keveyis and the rate of our future expenditures as well as our ability to obtain funding through strategic collaborations or grants. To become and remain profitable, we must successfully commercialize Keveyis and develop and eventually commercialize one or more of our product candidates with significant market potential.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. It may be several years, if ever, before we receive regulatory approval and have a product candidate other than Keveyis approved for commercialization. Our future revenue from Keveyis and from any other product candidates approved for commercialization will depend upon the size of the markets in which our product candidates are marketed, or in which they may receive approval, and our ability to achieve market acceptance and adequate market share for our product candidates in those markets.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We expect to continue to incur significant expenses and increasing operating losses until we successfully commercialize Keveyis and one or more of our product candidates. We anticipate that our expenses will increase substantially if and as we:

- establish a sales, marketing and distribution infrastructure to commercialize Keveyis and any other products for which we may obtain regulatory approval;
- continue research and nonclinical and clinical development of our product candidates, including advancing our programs from preclinical development into clinical trials and increasing the number and size of our current clinical trials and preclinical studies;
- make up-front, milestone or other payments under any asset acquisition, supply, or license arrangements;
- seek to identify, assess, in-license, acquire and develop additional product candidates;
- change or add manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- seek to maintain, protect and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a U.S. listed company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including, but not limited to, failed preclinical studies or clinical trials, complex results, safety issues or other regulatory challenges that may require either longer follow-up of existing preclinical studies or clinical trials or limitation of additional preclinical studies or clinical trials in order to pursue regulatory approval.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Moreover, if we incur substantial losses, we could be liquidated, and the value of our shares might be significantly reduced or the shares might be of no value.

We have never generated any revenue from product sales and may never be profitable.

We have only one product approved for commercialization, and two product candidates in development, and have never generated any revenue from product sales. We will not generate revenue from product sales unless and until we launch Keveyis or successfully complete the development of, obtain regulatory approval for and commercialize one or more of our product candidates. Our ability to generate future revenue from product sales and become profitable depends heavily on our success in many areas, including, but not limited to:

- integrating Keveyis and any other products or product candidates that we in-license or acquire, as well as completing research, formulation and process development, and preclinical or clinical development, as applicable, of those product candidates, including successfully completing clinical trials of those product candidates;
- obtaining regulatory approval of our product candidates;
- incurring additional costs as we advance our product candidates;
- developing a sustainable and scalable manufacturing process for our product candidates, if approved;

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- maintaining supply and manufacturing relationships with third parties that can conduct the manufacturing process development and provide adequate, in amount and quality, products to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of Keveyis and our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, in-licensing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Given the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond expectations if we are required by the FDA or the EMA, or any comparable foreign regulatory agency, to perform nonclinical and preclinical studies or clinical trials in addition to those that we currently anticipate.

We anticipate incurring significant costs associated with commercializing Keveyis and any other product candidates that are approved. Further, our revenue will be dependent, in part, upon the size of the markets in the territories for which we have received regulatory approval, the accepted price for the product, the ability to obtain coverage and adequate reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates. If we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to successfully execute any of the foregoing would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

We expect that we will need substantial additional funding before we can expect to complete the development of our two product candidates.

We are currently advancing two product candidates through clinical development, Recorlev (levoketoconazole and formerly called COR-003) and veldoreotide (formerly called COR-005). Development of product candidates is expensive, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our ongoing trials and initiate new nonclinical studies and clinical trials of Recorlev, veldoreotide and any other product candidates we may seek to develop. We expect that we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates.

As of December 31, 2016, we had cash and cash equivalents of $66.8 million. We currently believe that our existing cash and cash equivalents, excluding any additional borrowings under the credit facility, is sufficient to fund planned operations into 2019. However, this estimate is based on assumptions that may prove to be incorrect, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- the amount of revenue that we receive from sales of Keveyis;
- the cost and timing of establishing sales, marketing, distribution and administrative capabilities;

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of formulation, process development, manufacturing of clinical supplies, and establishing commercial supplies of our product candidates and any other product candidates that we may develop, in-license or acquire;
- whether we borrow any additional amounts under our $40 million credit facility;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our product candidates, if approved. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of product revenue, equity offerings, debt financings, grants, and license and development agreements in connection with any collaborations. Although we have borrowed only $20 million available under our $40 million credit facility, the remainder may be borrowed only if certain product revenue and clinical data milestones are achieved. We do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, the ownership interests of our current shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that would adversely affect their rights as shareholders. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Further, if we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We are expanding our organization and may experience difficulties in managing this growth, which could disrupt our operations.

As our development, commercialization, in-licensing, and acquisition plans and strategies develop, and as we commercialize Keveyis and advance the clinical and preclinical development of our product candidates, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of managerial, operational, sales, marketing, financial, legal and other resources. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any such growth could require significant capital expenditures and may divert financial resources from other projects, such as the in-licensing, acquisition and development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

In order to increase adoption and sales of Keveyis and other product candidates we may commercialize, we will need to continue developing our commercial organization as well as recruit and retain qualified sales representatives.

Part of our strategy is to continue to build a biopharmaceutical company to successfully execute the commercialization of our products. We may not be able to successfully commercialize our products in the United States or in any other territories where we have commercial rights. We do not have any experience commercializing products on our own. In order to commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Although we intend to establish an initial sales force consisting of approximately twelve orphan disease sales representatives, we currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our products and any additional products we may acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products will be harmed.

As we recently acquired U.S. marketing rights to Keveyis and hired our sales force, the members of our sales force will have limited experience promoting Keveyis. As a result, we will be required to expend significant time and resources to train our sales force to be effective in their sales efforts for Keveyis. For example, we must train our sales force to ensure that a consistent and appropriate message about Keveyis is being delivered to our potential customers. Our sales representatives may also experience challenges promoting Keveyis when we call on physicians and their office staff. We are likely to experience turnover of the sales representatives that we have hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate physicians about the benefits of our products and their proper administration and label indication, as well as our patient access programs, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We may not be successful in executing our research programs or business development efforts.

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs, business development efforts or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates;
- for product candidates we seek to in-license or acquire, we may not be able to agree to acceptable terms with the licensor or owner of those product candidates;
- our product candidates may not succeed in preclinical studies or clinical trials;
- we may not succeed in formulation or process development;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive regulatory approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates that we develop may be covered by third parties' patents or other exclusive rights;
- product candidates that we develop may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

If we acquire other businesses or in-license or acquire other product candidates and are unable to integrate them successfully, our financial performance could suffer.

If we are presented with appropriate opportunities, we may acquire other businesses or product candidates. We have had limited experience integrating other businesses or product candidates, or in-licensing or acquiring other product candidates. The recent acquisition of the U.S. marketing rights of Keveyis and our June 2015 acquisition of veldoreotide are still being integrated into our business. The integration process following these or any future transactions may produce unforeseen operating difficulties and expenditures, and may absorb significant management attention that would otherwise be directed to the ongoing development of our business. Also, in any future in-licensing or acquisition transactions, we may issue shares of stock that would result in dilution to existing shareholders, incur debt, assume contingent liabilities or create additional expenses related to amortizing intangible assets, any of which might harm our financial results and cause our stock price to decline. Any financing we might need for future transactions may be available to us only on terms that restrict our business or impose costs that reduce our net income.

We are highly dependent on our key personnel, including our chief executive officer and chief medical officer, as well as our ability to recruit, retain and motivate additional qualified personnel.

We are highly dependent on Matthew Pauls, our President and Chief Executive Officer, and Dr. Fredric Cohen, our Chief Medical Officer. Some members of our management team, including Mr. Pauls, have only been our employees since August 2014. As a result, they have limited experience working for us and working together as a team. Any member of management or employee can terminate his or her relationship with us at any time. Although we have included non-compete provisions in their respective employment or consulting agreements, as the case may be, such arrangements might not be sufficient for the purpose of preventing such key personnel from entering into agreements with any of our competitors. The inability to recruit and retain qualified personnel, or the loss of Mr. Pauls or Dr. Cohen, could result in competitive harm as we could experience delays in reaching our in-licensing, acquisition, development and commercialization objectives.

We also depend substantially on highly qualified managerial, sales and technical personnel who are difficult to hire and retain. There is currently a shortage of skilled personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our clinical research organizations, or CROs, and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, including hurricanes, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to Our Business

We depend entirely on the success of Keveyis and two product candidates, which are still in clinical development. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We currently have one product approved for sale and two product candidates in development. We have invested, and continue to expect to invest, a significant portion of our efforts and financial resources in the development of our two product candidates, which are still in clinical development. Our ability to generate product revenues will depend heavily on our successful commercialization of Keveyis and our eventual commercialization, if approved, of one or more of our product candidates currently in development. We are not permitted to market or promote any product candidate before we receive regulatory approval from the FDA, EMA or any comparable foreign regulatory agency, and we may never receive such regulatory approval for our product candidates currently in development. The success of Recorlev and veldoreotide will depend on several additional factors, including, but not limited to, the following:

- successfully completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- successfully completing formulation and process development activities;
- acceptance of our product candidates by patients and the medical community;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials or eventually commercialize our product candidates, if approved.

Clinical trials are very expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage clinical trials. For example, the results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for each of our product candidates and have not completed Phase 3 clinical trials for any of our product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

Companies in the biopharmaceutical industry may suffer setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. For example, levoketoconazole was previously studied for the treatment of type 2 diabetes. In December 2005, prior to the initiation of the first clinical trial by DiObex, our licensee, the FDA placed a clinical hold relating to a safety concern for use of a dosage above 600 mg/day. DiObex modified the clinical trial protocol to limit the highest dose to 600 mg/day, and the clinical hold was lifted by the FDA in February 2006. Furthermore, levoketoconazole did not demonstrate a reduction in blood glucose levels in a small Phase 2 clinical trial in patients with type 2 diabetes mellitus, the original indication for which it was being developed. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enrol an adequate number of subjects or patients on time or be completed on schedule, if at all. Clinical trials may be delayed, suspended or terminated for a variety of reasons, including delay or failure to:

- obtain authorization from regulators or institutional review boards, or IRBs, to commence a clinical trial at a prospective clinical trial site;

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- reach agreements on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- recruit and enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- have patients complete clinical trials or return for post-treatment follow-up;
- have CROs or other third parties comply with regulatory requirements, adhere to the trial protocol or meet contractual obligations in a timely manner or at all;
- identify a sufficient number of clinical trial sites and initiate them within the planned timelines; and
- manufacture sufficient quantities of the product candidate to complete clinical trials.

Positive or timely results from preclinical or early stage clinical trials do not ensure positive or timely results in late stage clinical trials or regulatory approval by the FDA, EMA or any comparable foreign regulatory agency. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the product candidates. The FDA, EMA and any comparable foreign regulatory agency have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or any comparable foreign regulatory agency.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the administration regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. In the case of our late stage clinical product candidates, results may differ in general on the basis of the larger number of clinical trial sites and additional countries involved in Phase 3 clinical trials. Different countries have different standards of care and different levels of access to care for patients, which in part drives the heterogeneity of the patient populations that enroll in our studies.

In June 2015, we acquired veldoreotide and were not involved in and had no control over the preclinical and clinical development of this product candidate prior to such acquisition. As a result, we are dependent on the prior research and development of veldoreotide having been conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, the accuracy of reported results of all clinical trials conducted prior to our acquisition and the correct interpretation of collected data from these clinical trials. These factors could result in increased costs and delays in the development of veldoreotide, which could hurt our ability to generate future revenues from this product candidate.

The regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time consuming and unpredictable.

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. Although certain of our employees have prior experience with submitting marketing applications to the FDA, EMA and comparable foreign regulatory agencies, we, as a company, have not submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Applications for any of our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to, the following:

- the FDA, EMA or any comparable foreign regulatory agency may disagree with the design or implementation of our clinical trials or our interpretation of data from nonclinical trials or clinical trials;

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval, including reliance on foreign clinical data;
- the data collected from clinical trials of our product candidates may not be sufficient to support a finding that has statistical significance or clinical meaningfulness or support the submission of a new drug application, or NDA, or other submission, or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or any comparable foreign regulatory agency that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or any comparable foreign regulatory agency may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or any comparable foreign regulatory agency may significantly change in a manner rendering our clinical data insufficient for approval.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Several elements of the SONICS Phase 3 clinical trial design for Recorlev were informed by the clinical development pathway of currently approved drug therapies in the United States and the European Union. Additionally, we incorporated advice from the CHMP and FDA into the design of the clinical trial. In communication we had with the FDA, they recommended use of a concurrent control group in SONICS. However, SONICS utilizes an open-label, single-arm design because use of a placebo control in a parallel-arm monotherapy design was considered unethical or infeasible to enroll, depending on the specific country or clinical trial site under consideration. Studies lacking an active control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. As a result, even if we achieve the clinical trial's endpoints, the FDA or other regulatory authorities could view our study results as potentially biased.

We intend to seek formal advice and guidance from the FDA and the EMA prior to advancing veldoreotide into further studies and pivotal clinical trials. If the feedback we receive is different from what we currently anticipate, this could delay the development and regulatory approval process for this product candidate.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

If we or others identify previously unknown, serious side effects of Keveyis, we may be required to perform lengthy additional clinical trials, change the labeling of Keveyis or withdraw it from the market.

If we or others identify previously unknown, serious side effects of Keveyis:

- regulatory authorities may withdraw their approvals;
- we may be required to conduct additional clinical trials, make changes in labeling, implement changes to or obtain re-approvals of facilities that manufacture Keveyis;
- we may experience a significant drop in the sales of Keveyis;
- our reputation in the marketplace may suffer; and

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- we may become the target of lawsuits, including class action lawsuits.

Any of these events could harm or prevent sales of Keveyis or could increase the costs and expenses of commercializing and marketing Keveyis.

Physicians may accept Keveyis slowly or may never accept it, which would adversely affect our financial results.

Physicians will prescribe Keveyis only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is preferable to other treatments, even if those products are not approved for primary periodic paralysis. Because primary periodic paralysis is rare, most physicians are inexperienced in the care of patients with the illness and it may be difficult to persuade them to prescribe Keveyis.

Other factors that may affect the commercial success of Keveyis include:

- the preference of some physicians for more familiar, long-standing, off-label treatments for primary periodic paralysis, such as acetazolamide
- competition from alternative therapies, such as potassium supplements, diuretics, beta receptor agonists, mexiletine and other sodium channel blockers;
- the cost-effectiveness of Keveyis and the availability of third-party insurance coverage and reimbursement; and
- the product labeling required by the FDA.

The failure of Keveyis to achieve commercial success could prevent us from generating sufficient revenue to fully fund our commercial and development activities.

If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following regulatory approval, if any, we may need to abandon our development of such product candidates.

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in preclinical or early stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

For example, in our clinical trials of Recorlev to date, adverse events have included headache, nausea, back pain, dizziness, diarrhea and liver enzyme elevations. For veldoreotide, which is given by subcutaneous injections, adverse events have included injection site reaction such as swelling, itching and pain. In addition, headache and gastrointestinal effects such as nausea and diarrhea were observed for veldoreotide. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy. Occurrence of serious treatment-related side effects could impede clinical trial enrollment, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA, EMA or any comparable foreign regulatory agency. They could also adversely affect physician or patient acceptance of our product candidates.

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market. Currently, ketoconazole is required to include a “black box” warning on its label for use as an antifungal related to liver toxicity in the United States. Manufactured ketoconazole consists of two enantiomers, 2R,4S-ketoconazole and 2S,4R-ketoconazole, that are found in equal amounts, and is therefore referred to as a racemate mixture. Recorlev is a single-enantiomer drug, a pure form of one of the two enantiomers (2S,4R-ketoconazole) of ketoconazole. If Recorlev is required to include a similar “black box” warning on its label, it may limit our ability to commercialize the product, if approved.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Additionally, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product(s), a number of potentially significant negative consequences could result, including, but not limited to:

- withdrawal by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product;
- requirement by regulatory authorities of additional warnings on the label, such as a black box warning;
- requirement that we create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to launch as a prerequisite of approval by regulatory authorities of such product;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- initiation of legal action against us claiming to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for the treatment of which our product candidates are being studied. Difficulty in enrolling patients in our clinical trials could delay or prevent clinical trials of our product candidates.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the safety and potential advantages of the product candidate being studied in relation to other available therapies.

Because we are focused on addressing rare diseases, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may become exposed to costly and damaging liability claims, either in connection with the sale of Keveyis or other approved products or when testing our product candidates in the clinic, and our product liability insurance may not cover all damages from such claims.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. Our first commercial product is Keveyis. The current and future use of product candidates by us in clinical trials, and the sale of Keveyis and any approved products, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend, and could compromise the market acceptance of Keveyis, our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If Keveyis or any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use Keveyis or our product candidates.

We have limited product liability insurance that offers coverage we believe to be appropriate for a company marketing a single pharmaceutical product and developing others. We intend to extend our product liability insurance coverage to any product candidate for which we obtain marketing approval. However, this insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of Keveyis or our product candidates, or result in meaningful underinsured or uninsured liability. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business. If we were sued successfully, our liability could exceed our total assets.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with suitable partners.

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, in-licensing or acquiring our product candidates, identifying potential product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have a very limited sales force and marketing and distribution capabilities. To achieve commercial success of Keveyis and any product candidates that are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize Keveyis and our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of Keveyis and our product candidates, we may not generate revenues from them.

We operate in a highly competitive and rapidly changing industry, which may result in our competitors discovering, developing or commercializing competing products before or more successfully than we do, or our entering a market in which a competitor has commercialized an established competing product, and we may not be successful in competing with them.

The development and commercialization of new drug products is highly competitive and subject to significant and rapid technological change. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative drug products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Keveyis is an oral carbonic anhydrase inhibitor, that was approved in the United States to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis (PPP). Acetazolamide, another oral carbonic anhydrase inhibitor, is used frequently off-label for the prophylactic and sometimes acute treatment of PPP. Potassium supplements, are indicated for use in hypokalemic periodic paralysis in the United States and are frequently used either chronically or for emergency treatment of episodes in that form of PPP. Several other types of drugs have been reported to have benefits for chronic or acute use in one or more than one PPP variant, including potassium-sparing diuretics, beta receptor agonists, mexelitine and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP. A Phase 2 clinical study of bumetanide, a loop diuretic, is underway in England for acute treatment of paralytic attacks.

We are currently aware of various companies that are marketing existing drugs that may compete with Recorlev such as Corcept Therapeutics and Novartis. The treatment of endogenous Cushing's syndrome patients who fail or are ineligible for surgery in the United States and Europe are: Korlym (mifepristone) marketed by Corcept Therapeutics in the United States; Signifor (pasireotide) marketed by Novartis in the United States and European Union; and ketoconazole, metyrapone and mitotane marketed by HRA in the European Union. Novartis has submitted an NDA/MAA for Signifor (pasireotide) LAR in Cushing's disease. Additionally, LCI-699 (osilodrostat) is currently in Phase 3 clinical development by Novartis in Cushing's disease patients. Corcept is developing CORT125134, a second-generation glucorticoid receptor modulator; currently in Phase 2. HRA Pharma is developing metyrapone for the US market; currently in Phase 2. Millendo is developing ATR-101, a selective acyl-CoA:cholesterol acyltransferase 1 (ACAT) inhibitor, currently in Phase 2. In addition, Ketoconazole is the most commonly prescribed drug therapy for the treatment of endogenous Cushing's syndrome, even though it is not approved for this use in the United States. Regulatory approval of ketoconazole in the United States for the treatment of endogenous Cushing's syndrome could significantly increase competition for Recorlev due to their similar mechanisms of action.

We are currently aware of various companies that are marketing existing drugs that may compete with veldoreotide such as Novartis, Ipsen and Pfizer. In addition, a number of acromegaly therapies are in various stages of development. There are currently three approved SSA therapies for acromegaly in the United States: Sandostatin LAR (octreotide) marketed by Novartis; Signifor LAR (pasireotide) marketed by Novartis; and Somatuline Depot (lanreotide) marketed by Ipsen. There is one growth hormone receptor antagonist, Somavert (pegvisomant), marketed by Pfizer. Chiasma had filed an NDA in the U.S. for RG-3806 (Mycapssa®), an oral octreotide formulation in 2015, and received a Complete Response Letter wherein FDA stated that it did not believe the company's application had provided substantial evidence of efficacy to warrant approval, and advised Chiasma that it would need to conduct another clinical trial in order to overcome this deficiency. Four additional therapies are in Phase 2 clinical development for acromegaly: octreotide long-acting depot (CAM-2029) developed by Novartis and Camurus; ITF-2984 developed by Italfarmaco; BIM-23B065 developed by Ipsen; and ATL-1103 developed by Antisense Therapeutics.

We anticipate this competition to increase in the future as new companies enter the neuromuscular, endocrinology and rare diseases markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our products obsolete.

The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete or non-competitive. Our competitors may, among other things:

- have similar or better product candidates or technologies;
- possess greater financial and human resources as well as supporting clinical data;
- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain regulatory approval more quickly;
- establish superior proprietary positions;
- have access to greater manufacturing capacity;
- seek patent protection that competes with our product candidates;

- implement more effective approaches to sales and marketing; or
- enter into more advantageous collaborative arrangements for research, development, manufacturing and marketing of products.

Additional competitors could enter the market with generic versions of our products, which may result in a decline in sales of affected products.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Hatch-Waxman also provides for certain periods of regulatory exclusivity, which preclude FDA approval, or, in some circumstances, FDA filing and reviewing, of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. Although Recorlev is being developed as a new chemical entity, or NCE, we intend to rely on orphan drug exclusivity rather than NCE exclusivity for nonpatent protection of Recorlev. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if Recorlev or any of our other product candidates is approved, competitors could file ANDAs for generic versions of our product candidates, or 505(b)(2) NDAs that reference our product candidates, respectively. If there are patents listed for our product candidates in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our ability to generate revenue could be compromised.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies. The successful commercialization of Keveyis and our product candidates, if approved, will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new therapies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage and adequate reimbursement to such new technologies. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs.

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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for Keveyis and/or any product candidate that we commercialize, and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for Keveyis and/or our product candidates, our ability to generate revenue will be compromised.
Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support, medical necessity or both for the use of Keveyis or any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness, medical necessity or both of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results.

Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product, but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases on short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact such favorable coverage and reimbursement status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could negatively affect the market acceptance of Keveyis and our product candidates and the future revenues we may expect to receive from these products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

Our products may not gain market acceptance, in which case we may not be able to generate product revenues.

Even if the FDA, EMA or any comparable foreign regulatory agency approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our products or product candidates may require significant resources and may not be successful. If Keveyis, Recorlev, veldoreotide or any other product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of Keveyis, Recorlev, veldoreotide or any other product candidates that are approved for commercial sale will depend on a variety of factors, including, but not limited to:

- whether clinicians and potential patients perceive our products or product candidates to have better efficacy, safety and tolerability profile, and ease of use compared with alternative therapies;
- the timing of market introduction;
- the number of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support; and
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors, both public and private.

In addition, the potential market opportunity for Keveyis, Recorlev, veldoreotide or any other product candidate we may develop is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for Keveyis, Recorlev or our other product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for Keveyis, Recorlev or our other product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our product revenue may be limited and we may be unable to achieve or maintain profitability. Further, given the limited number of treating physicians, if we are unable to convince a significant number of such physicians of the value of our products or product candidates, we may be unable to achieve a sufficient market share to make our products profitable.

The Orphan Drug designation for Keveyis and our product candidates may not prevent competition from companies that develop other compounds for the treatment of the same condition. These companies may have significantly more resources than we do. Competition from them could limit our revenue from the commercialization of Keveyis and/or our other product candidates.

Although Keveyis and our product candidates have received Orphan Drug designation in the United States, and in the case of Recorlev and veldoreotide in Europe, we cannot be assured that we will realize the potential benefits of the designation. Even after an orphan drug is approved for its orphan indication, the FDA or EMA can subsequently approve a different drug for the same condition if it concludes that the later drug is safer, more effective or makes a major contribution to patient care. Upon expiration of the orphan drug exclusivity period, we may be subject to competition from manufacturers offering a generic form of Keveyis or our other products at a lower price, in which case our business could be harmed.

For example, Corcept's Korlym has an Orphan Drug designation in the United States and is approved for the control of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed surgery or are not candidates for surgery. However, in 2012 Novartis received approval in both the United States and the European Union (EU) to market its somatostatin analogue Signifor for adult patients with Cushing's disease (a subset of Cushing's syndrome that accounts for approximately 70 percent of all Cushing's syndrome patients) for whom pituitary surgery is not an option or has not been curative.

Laboratoire HRA Pharma (HRA) received Orphan Drug designation in the United States and the EU for the use of mifepristone to treat a subtype of Cushing's syndrome. HRA began and terminated a Phase 2 clinical trial in Europe and the United States for this indication. Exelgyn Laboratories, which operates as a subsidiary of Medi Challenge (Pty) Ltd., received Orphan Drug designation for mifepristone to treat Cushing's syndrome in the EU, but it has stated that it has not yet conducted any clinical trials.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

The terms of our credit facility place restrictions on our operating and financial flexibility.

The Loan Agreement with Oxford and Horizon includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and good standing and governmental approvals necessary for us and our subsidiaries to perform our respective businesses and obligations under the Loan Agreement, deliver certain financial reports to the Lenders, maintain insurance coverage, comply with certain financial covenants, dissolve our subsidiary, BioPancreate Inc., within six months of the effective date of the Loan Agreement, and enter into an intercompany license or other agreement with our subsidiary, Strongbridge U.S. Inc., pursuant to which Strongbridge U.S. Inc. will have the exclusive right to market and sell Keveyis products in the United States. The negative covenants include, among others, restrictions on our transferring collateral, changing our business, management, ownership or business location, engaging in mergers or acquisitions, incurring additional indebtedness, paying dividends or making other distributions, making investments, creating liens, or entering into transactions with affiliates, in each case subject to certain exceptions.

The Loan Agreement also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the Loan Agreement, a breach of covenants under the Loan Agreement, a material adverse change, our insolvency, the occurrence of a default under any agreement with a third party that would result in a payment by us or our subsidiaries of greater than $100,000, and/or one or more judgments against us or our subsidiaries in an amount greater than $100,000 individually or in the aggregate.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Risks Related to Our Reliance on Third Parties

We have no manufacturing capabilities and currently depend on one supplier to manufacture Keveyis. We also depend on a limited number of other suppliers to manufacture our product candidates for use in clinical trials. If these suppliers are unable or unwilling to continue manufacturing for us and we are unable to contract quickly with alternative sources, or if these third-party manufacturers fail to comply with FDA regulations or otherwise fail to meet our requirements, our business will be harmed.

Taro Pharmaceuticals North America, Inc., Inc. produces all of our requirements of Keveyis. We rely on other third-parties to manufacture our product candidates for use in clinical trials. If any of these vendors is unable or unwilling to meet our future requirements, we may not be able to manufacture our products in a timely manner. Our current arrangements with these manufacturers are terminable by such manufacturers, subject to certain notice provisions.

The facilities used by our vendors to manufacture our product and product candidates must be approved by the FDA. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements known as current good manufacturing practices (cGMPs). If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our products or if it withdraws any such approval, we may need to find alternative manufacturing facilities, which would significantly hamper our ability to develop, obtain regulatory approval for or market our products.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

In addition, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. If our suppliers fail to manufacture Keveyis or our product candidates on a timely basis in the quantities that we require, or fail to maintain manufacturing capabilities that meet FDA standards, we may exhaust our Keveyis inventory and not be able to generate revenue, or clinical development programs may be delayed.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing of Keveyis and our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our products and product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an NDA or foreign equivalent on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers have never produced a commercially-approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

If we, our collaborators or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or another applicable regulatory authority could impose regulatory sanctions including, among other things, refusal to approve a pending application our product candidates, withdrawal of an approval or suspension of production.

Additionally, if the supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We rely on third parties to conduct our nonclinical and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct and monitor and manage data for our ongoing nonclinical and clinical programs, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROS, we will have only limited control over their actual performance of these activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, environmental and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs and other vendors are required to comply with current Good Manufacturing Practices, or cGMP, current Good Clinical Practices, or cGCP, and Good Laboratory Practice, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory agency for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, trial sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our nonclinical and clinical trials may be deemed unreliable and the FDA, EMA or any comparable foreign regulatory agency may require us to perform additional nonclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our business involves the controlled use of hazardous materials, chemicals, biologicals and radioactive compounds. Substantially all such use is outsourced to third-party CRO manufacturers and clinical sites. Although we believe that our third-party CROs safety procedures for handling and disposing of such materials comply with industry standards, there will always be a risk of accidental contamination or injury. By law, radioactive materials may only be disposed of at certain approved facilities. If liable for an accident, or if it suffers an extended facility shutdown, we or our CROs could incur significant costs, damages or penalties.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Our CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If we are able to replace a CRO, switching or adding additional CROs involves additional cost and requires management time and focus and there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could hurt our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

Risks Related to Our Intellectual Property

If we or our licensors are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

In addition to the exclusivity provided for Keveyis and our product candidates with regulatory orphan drug status, we rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We have sought to protect our proprietary position by filing, where possible, patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development and manufacturing processes before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products or product candidates in the United States or in foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to file any patent application related to our products or product candidates, or whether we were the first to make the inventions claimed in our owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We and/or our licensors or partners have filed several patent applications covering various aspects of our products and product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any products or product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced.

We may not have sufficient patent terms to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our products or product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

Although patent term extensions in the United States and under supplementary protection certificates in the European Union may be available to extend the patent exclusivity term for our products or product candidates, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the AIA, enacted on September 16, 2011, the United States has moved to a first inventor to file system. The AIA also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the United States Patent and Trademark Office, or the USPTO, is still implementing various regulations, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell Keveyis and our product candidates, if approved, and use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will market Keveyis and are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of Keveyis or our product candidates. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of Keveyis or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize Keveyis or one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe upon our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable, or request declaratory judgment that there is no infringement. In patent litigation in the United States, defendant counterclaims alleging invalidity, noninfringement and/or unenforceability are commonplace.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, nonobviousness or non-lack of enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs, and distract our management and other employees. In addition, the uncertainties associated with litigation could compromise our ability to successfully market Keveyis, raise the funds necessary to continue our clinical trials, continue our research programs, and license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market, if approved.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the market price of our ordinary shares.

Failure to secure or maintain adequate protection for our trademarks could adversely affect our business.

We have filed a U.S., Canadian, Brazilian and International (Madrid Protocol) trademark application designating Australia, China, European Community, India, Israel, Japan, Mexico and Turkey for the mark, “Strongbridge Biopharma.” If the U.S. or any foreign trademark offices raise any objections, we may be unable to overcome such objections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Oppositions or cancellation proceedings have been filed and may in the future be filed against our trademarks, and our trademarks may not survive such proceedings.

Furthermore, third parties may allege in the future, that a trademark or trade name that we elect to use for our product candidates may cause confusion in the marketplace. We evaluate such potential allegations in the course of our business, and such evaluations may cause us to change our commercialization or branding strategy for our product candidates, which may require us to incur additional costs. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Failure to secure or maintain adequate protection for our trademarks could adversely affect our business.

We have filed a U.S., Canadian, Brazilian and International (Madrid Protocol) trademark application designating Australia, China, European Community, India, Israel, Japan, Mexico and Turkey for the mark, “Strongbridge Biopharma.” If the U.S. or any foreign trademark offices raise any objections, we may be unable to overcome such objections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Oppositions or cancellation proceedings have been filed and may in the future be filed against our trademarks, and our trademarks may not survive such proceedings.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Furthermore, third parties may allege in the future, that a trademark or trade name that we elect to use for our product candidates may cause confusion in the marketplace. We evaluate such potential allegations in the course of our business, and such evaluations may cause us to change our commercialization or branding strategy for our product candidates, which may require us to incur additional costs. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names or copyrights may be ineffective and could result in substantial costs and diversion of resources.

In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks alleging that the use of a corporate name or logo, product names or other signs by which we distinguish our products and services are infringing their trademark rights. The outcome of such claims is uncertain and may adversely affect our freedom to use our corporate name or other relevant signs. If litigation arises in this area, it may lead to significant costs and diversion of management and employee attention.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Government Oversight and Regulation

We will be subject to ongoing obligations and continued regulatory requirements, which may result in significant additional expense.

Keveyis and any of our product candidates that obtain regulatory approval will remain subject to continual regulatory review. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, the EMA or any comparable foreign regulatory authority approves any of our product candidates, we will be subject to ongoing regulatory obligations and oversight by regulatory authorities, including with respect to the manufacturing processes, labeling, packing, distribution, adverse event reporting, storage, advertising and marketing restrictions, and recordkeeping and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-regulatory approval. Because our two Phase 3 clinical trials of Recorlev will collect safety data for approximately 125 patients, we currently expect that we would be required by the FDA and the EMA to collect additional safety data post-approval.

In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market, or voluntary or mandatory product recalls;

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

- fines, disgorgement of profits or revenues, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements. The policies of the FDA, the EMA or any comparable foreign regulatory agency may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would compromise our ability to achieve or sustain profitability.

Although we have obtained orphan drug designation for Keveyis and our key product candidates from the FDA and EMA, orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug exclusivity for Keveyis or our product candidates, we may be subject to earlier competition and our potential revenue will be reduced.

Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is intended to treat an orphan disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as a reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Keveyis has been granted orphan drug designation for the treatment of hyperkalemic, hypokalemic, and related variants of primary periodic paralysis in the United States. Recorlev has been granted orphan drug designation for the treatment of endogenous Cushing's syndrome in the United States and Europe. Veldoreotide has been granted orphan drug designation for the treatment of acromegaly in the United States and in Europe. Even though we have obtained orphan drug designation for our key product candidates, we may not be the first to obtain regulatory approval for any particular orphan indication due to the uncertainties associated with developing biopharmaceutical products. For example, ketoconazole was granted orphan drug exclusivity in Europe and is now being marketed for the treatment of endogenous Cushing's syndrome.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Therefore, Recorlev will need to show significant benefit compared to ketoconazole in order to be marketed in Europe prior to the expiration of the ketoconazole orphan drug exclusivity. Further, even though we have obtained orphan drug designation for our key product candidates, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates, and may affect the prices we may set.

In the United States and the European Union, there have been a number of legislative, regulatory and proposed changes regarding the healthcare system. These changes could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to sell profitably any products for which we obtain regulatory approval and begin to commercialize.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. In the United States, the Medicare Modernization Act changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow the Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, a sweeping law intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. PPACA, among other things: increased the statutory minimum Medicaid rebates a manufacturer must pay under the Medicaid Drug Rebate Program; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; and established a new Medicare Part D coverage gap discount program in which manufacturers must provide 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer’s outpatient drugs to be covered under Part D and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the PPACA imposed a significant annual nondeductible fee on entities that manufacture or import specified branded prescription drug products and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. We expect that additional healthcare reform measures will likely be adopted in the future, any of which may increase our regulatory burdens and operating costs and limit the amounts that federal, state and foreign governments will reimburse for healthcare products and services, which could result in reduced demand for our products, if approved, or additional pricing pressures.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Moreover, other legislative changes have also been proposed and adopted in the United States since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021 was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could compromise the ability of patients and third-party payors to purchase our product candidates.

In 2017, the U.S. Congress has been assessing new legislation designed to repeal and replace core sections of the PPACA. We expect the U.S. Congress to continue to review and assess this legislation, referred to as the American Health Care Act (AHCA), along with other alternative health care reform proposals throughout 2017. Recent Congressional efforts such as the AHCA proposal adds to the uncertainty of the legislative changes enacted as part of PPACA. These changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In the European Union, proposed new clinical trial regulations will centralize clinical trial approval, which eliminates redundancy, but in some cases this may extend timelines for clinical trial approvals due to potentially longer wait times. Proposals to require specific consents for use of data in research, among other measures, may increase the costs and timelines for our product development efforts. Austerity measures in certain European nations may also affect the prices we are able to seek if our products are approved, as discussed below.

Both in the United States and in the European Union, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be.

Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.

Pharmaceutical product pricing is subject to enhanced government and public scrutiny and calls for reform. There has recently been intense publicity regarding the pricing of pharmaceutical products generally, including publicity and pressure resulting from the prices charged for new products as well as price increases for older products that the government and public deem excessive. We may experience downward pricing pressure on the price of our products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability. In addition, many companies in our industry have received governmental requests for documents and information relating to drug pricing and patient support programs. If we were to become subject to similar requests, we could incur significant expense and experience reputational harm, as well as reduced market acceptance and demand for our products, which could harm our ability to market our products in the future. These factors could also result in changes in our product pricing and distribution strategies, reduced demand for our products and/or reduced reimbursement of products, including by federal health care programs such as Medicare and Medicaid and state health care programs. In addition, the Trump Administration has indicated an interest in taking measures pertaining to drug pricing, including potential proposals relating to Medicare price negotiations, and importation of drugs from other countries. At this time, it is unclear whether any of these proposals will be pursued and how they would impact our products or our future product candidates.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Our relationships with customers, consultants and payors will be subject to applicable fraud and abuse, privacy and security, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we may in the future obtain regulatory approval and commercialize. Our current and future arrangements with third-party payors, consultants, customers, physicians and others may expose us to broadly applicable fraud and abuse and other healthcare federal and state laws and regulations, including in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain regulatory approval. Potentially applicable healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, purchasing, leasing, ordering, arranging for, or recommending the purchase, lease, or order of, any good, facility, item or service for which payment may be made under U.S. government healthcare programs such as Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;

- the Privacy Rule or the Security Rule of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose various obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the health care fraud provisions of HIPAA, which impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services;

- the federal Physician Payments Sunshine Act under PPACA and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals, and ownership and investment interests held by physicians or their immediate family members; and

- analogous laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements, research, distribution and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state requirements for manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and other restrictions on drug manufacturer marketing practices.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute and analogous state laws, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, PPACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to be in violation. Moreover, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, imprisonment, disgorgement, enhanced government reporting and oversight, contractual damages, reputational harm, diminished profits and future earnings and/or the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management’s attention from the operations of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties, including, without limitation, criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities.

Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Risks Related to Our Ordinary Shares

The price of our ordinary shares may be volatile and may fluctuate due to factors beyond our control.

The market price of our ordinary shares may be volatile and subject to wide fluctuations in response to a variety of factors, many of which are beyond our control, including:

- revenues from sales of Keveyis;
- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in in-licensing or acquiring additional complementary product candidates;
- any delay in the commencement, enrollment and the ultimate completion of clinical trials;
- technological innovations or commercial product introductions by us or competitors;
- failure to successfully develop and commercialize any of our product candidates, if approved;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts; or
- general market conditions in the pharmaceutical industry or in the economy as a whole.

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may hurt the market price of companies' stock, including ours, regardless of actual operating performance.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ordinary shares and our trading volume could decline.

The trading market for our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts commence or continue coverage of our company, the trading price for our ordinary shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Future sales, or the possibility of future sales, of a substantial number of our ordinary shares could adversely affect the price of our ordinary shares.

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. We currently have 35,335,026 ordinary shares outstanding. We have also filed a Registration Statement on Form S-8, registering all ordinary shares that we may issue under our equity compensation plans. These ordinary shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements. If a large number of our ordinary shares or securities convertible into our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

An active market in our ordinary shares may not be liquid enough for investors to resell our ordinary shares.

The listing of our ordinary shares on the NASDAQ Global Select Market does not assure that a meaningful, consistent and liquid trading market exists. In general trading volume in our ordinary shares has been limited and an active trading market for our shares may not be sustained. If an active market for our ordinary shares is not sustained, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all.

We have never paid cash dividends, do not expect to pay dividends in the foreseeable future and our ability to pay dividends, or repurchase or redeem our ordinary shares, is limited by law.

We have not paid any dividends since our inception and do not anticipate paying any dividends on our ordinary shares in the foreseeable future. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. The proposal to pay future dividends to shareholders will in addition effectively be at the sole discretion of our board of directors after taking into account various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitations under the Irish Companies Act 2014.The Irish Companies Act, among other requirements, requires Irish companies to have distributable reserves available for distribution equal to or greater than the amount of the proposed dividend. Accordingly, investors cannot rely on dividend income from our ordinary shares and any returns on an investment in our ordinary shares will likely depend entirely upon any future appreciation in the price of our ordinary shares.

We *believe we were classified as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes in past years and we may be classified as a PFIC in future years, which could result in adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.*

A non-U.S. corporation generally will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year if either (1) 75% or more of its gross income for such year consists of certain types of "passive" income or (2) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. For this purpose, "passive income" generally includes, among other items of income, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income, and a non-U.S. corporation is treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which such non-U.S. corporation owns, directly or indirectly, more than 25% of the value of such other corporation's stock. Based on our income, assets and activities in past years, we believe that we were a PFIC in past years, and we may be classified as a PFIC for the current taxable year and for future years depending on the income, assets, and activities in such taxable years. A U.S. Holder that holds ordinary shares during any taxable year in which we are a PFIC would be subject to substantially increased U.S. federal income tax liability, including upon the receipt of any "excess distributions" from us and upon the sale or other disposition of our ordinary shares. Although certain elections may be available to mitigate the adverse impact of the PFIC rules, such elections may result in a current U.S. federal tax liability prior to any distribution on or disposition of our ordinary shares. Further, there can be no assurances that we will supply U.S. Holders with information that such U.S. Holders are required to report under the rules governing such elections. Accordingly, the acquisition of our ordinary shares may not be an appropriate investment for certain holders that are not tax-exempt organizations. U.S. Holders should consult their tax advisers regarding the application of the PFIC rules to an investment in our ordinary shares.

DIRECTORS' REPORT (CONTINUED)
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PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Irish laws and regulations with regard to such matters and intend to furnish quarterly financial information to the U.S. Securities and Exchange Commission (the "SEC), we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including: (1) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act; (2) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (3) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of NASDAQ, we may rely on certain home country governance practices rather than the corporate governance requirements of NASDAQ.

We are a foreign private issuer. As a result, in accordance with NASDAQ Listing Rule 5615(a)(3), we comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of NASDAQ.

Irish law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to NASDAQ Listing Rule 5605(b)(1). In addition, we are not subject to NASDAQ Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

Our Articles of Association (hereinafter referred to as our Articles) provide that at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy, but no such proxy shall be voted or acted upon at any subsequent meeting, unless the proxy expressly provides for this. Irish law does not require shareholder approval for the issuance of securities in connection with the establishment of or amendments to equity-based compensation plans for employees. To this extent, our practice varies from the requirements of NASDAQ Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. Losing our status as a foreign private issuer would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (1) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (2)(A) a majority of our executive officers or directors may not be United States citizens or residents, (B) more than 50% of our assets cannot be located in the United States and (C) our business must be administered principally outside the United States. If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

Our shareholder's rights are governed by Irish law and differ from the rights of shareholders under U.S. law.

We are a public limited company incorporated under the laws of Ireland. Therefore, the rights of holders of ordinary shares are governed by Irish law and by our memorandum and articles of association. These rights differ from the typical rights of shareholders in U.S. corporations. In certain cases, facts that, under U.S. law, would entitle a shareholder in a U.S. corporation to claim damages may not give rise to a cause of action under Irish law entitling a shareholder in an Irish company to claim damages. For example, the rights of shareholders to bring proceedings against us or against our directors or officers in relation to public statements are more limited under Irish law than under the civil liability provisions of the U.S. securities laws.

Our shareholders may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the United States, judgments obtained in the U.S. courts under the U.S. securities laws. In particular, if a shareholder sought to bring proceedings in Ireland based on U.S. securities laws, the Irish court might consider that:

- it did not have jurisdiction;
- it was not the appropriate forum for such proceedings;
- applying Irish conflict of laws rules, U.S. laws (including U.S. securities laws) did not apply to the relationship between you and us or our directors and officers; or
-
- the U.S. securities laws were of a penal nature or violated Irish public policy and should not be enforced by the Irish court.

Our shareholders should also be aware that Irish law does not allow for any form of legal proceedings directly equivalent to the class action available in the United States.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Because the PCAOB is not permitted to inspect registered public accounting firms in Ireland, you do not have the benefit of such inspections to the extent our financial statements are audited by a registered public accounting firm in Ireland.

Auditors of U.S. public companies, including our independent registered public accounting firm, are required by the laws of the United States to undergo periodic PCAOB inspections to assess their compliance with U.S. law and professional standards in connection with performance of audits of financial statements filed with the SEC. The laws of certain European Union countries, including Ireland, do not currently permit the PCAOB to conduct inspections of accounting firms established and operating in such European Union countries. Accordingly, to the extent our financial statements will be audited by a registered public accounting firm in Ireland, the PCAOB would be prevented from fully evaluating the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures. Unlike shareholders or potential shareholders of most U.S. public companies, our shareholders would be deprived of the possible benefits of such PCAOB inspections.

A future transfer of our ordinary shares, other than one effected by means of the transfer of book-entry interests in DTC, may be subject to Irish stamp duty.

The rate of Irish stamp duty, when applicable, on the transfer of shares in an Irish-incorporated company is 1% of the price paid, or the market value of the shares acquired, whichever is greater. Payment of Irish stamp duty is generally a legal obligation of the transferee. We expect that most of our ordinary shares will be traded through the Depositary Trust Company, or DTC, or through brokers who hold such shares on behalf of customers through DTC. As such, the transfer of ordinary shares should be exempt from Irish stamp duty based on established practice of the Irish Revenue Commissioners. We received written confirmation from the Irish Revenue Commissioners on June 22, 2015 that a transfer of our ordinary shares held through DTC and transferred by means of a book-entry interest would be exempt from Irish stamp duty. However, if you hold your ordinary shares directly of record, rather than beneficially through DTC, or through a broker that holds your ordinary shares through DTC, any transfer of your ordinary shares may be subject to Irish stamp duty. The potential for Irish stamp duty to arise could adversely affect the price and liquidity of our ordinary shares. In addition, the terms of our eligibility agreement with DTC requires us to provide certain indemnities relating to Irish stamp duty to third parties. If liability were to arise as a result of the indemnities provided under the terms of the eligibility agreement, we may face significant unexpected costs.

Anti-takeover provisions in our Articles and under Irish law could make an acquisition of us more difficult, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.

Our Articles contain provisions that may delay or prevent a change of control, discourage bids at a premium over the market price of our ordinary shares and adversely affect the market price of our ordinary shares and the voting and other rights of the holders of our ordinary shares. These provisions include:

- dividing our board of directors into three classes, with each class serving a staggered three-year term;
- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions which allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- establishing an advance notice procedure for shareholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; and
- the ability of our board of directors to fill vacancies on our board in certain circumstances.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

These provisions do not make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.

We are subject to the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (1) the issue of shares, options, restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in the United States.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, exemptions from the requirements to provide certain executive compensation disclosures, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation or seeking shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," in our initial registration statement, we were required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an "emerging growth company" as of the following December 31, our fiscal year end. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

Certain provisions of the warrants issued in the 2016 Private Placement could impede a sale of the Company.

In the event of a sale of the Company, the terms of the warrants issued to the 2016 Investors in the 2016 Private Placement require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrant agreements). Such payment must be made in cash in the event that the acquisition results in our shareholders receiving cash from the acquirer at the closing of the transaction, and must be made in shares of the Company (with the value of each ordinary share determined according to the calculation specified in the warrant agreements) in the event that the acquisition results in our shareholders receiving shares in the acquirer or other entity at the closing of the transaction. In the event that our shareholders receive both cash and shares at the closing of the transaction, such payment to the warrant holders shall also be made in both cash and shares in the same proportion as the consideration received by the shareholders.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Notwithstanding the foregoing, in the event that as a result of an acquisition the warrants will be exercisable for anything other than shares or securities that are listed on a regulated market (within the meaning of the Markets in Financial Instruments Directive (2004/39(EC))) or a United States national securities exchange, the warrant holders will be entitled to demand to receive a cash payment in an amount equal to the Black-Scholes Value per warrant (calculated in accordance with the warrants) contemporaneously with or promptly after the consummation of such acquisition.

We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate the identified material weaknesses, or if we otherwise fail to maintain effective internal control over financial reporting and disclosure controls and procedures, we may not be able to accurately report our financial results, detect or prevent fraud, or file our periodic reports in a timely manner, which may, among other adverse consequences, cause investors to lose confidence in our reported financial information and lead to a decline in our stock price.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. We are required under Section 404(a) of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2016, we concluded that there was a material weakness in the design and operating effectiveness of our internal control over our valuation of our warrants that were issued in connection with our private placement of ordinary shares. As defined in SEC Regulation S-X, a material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. The initial calculation was performed with incorrect inputs, therefore resulting in an adjustment to our consolidated financial statements included. As a consequence of this material weakness, management concluded that our internal control over financial reporting, and consequently our disclosure controls and procedures, were not effective as of December 31, 2016.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

RESULTS AND DIVIDENDS

The result for the year and the financial position at the end of the year are disclosed on pages 54 - 97. The following table sets forth our results of operations for the years ended December 31, 2016 and 2015.

	Year Ended December 31, 2016	Year Ended December 31, 2015	Change
	$'000	$'000	$'000
Operating expenses:			
Research and development	20,023	20,135	(112)
General and administrative	14,875	22,719	(7,844)
Impairment of intangible assets	15,828	-	15,828
Total operating expenses	50,726	42,854	7,872
Operating loss	(50,726)	(42,854)	(7,872)
Other (expense) income, net	(631)	(1,229)	598
Loss before taxes	(51,357)	(44,083)	(7,274)
Tax benefit	2,638	450	2,188
Net loss	(48,719)	(43,633)	(5,086)
Net loss attributable to non-controlling interest	122	53	69
Net loss attributable to ordinary shareholders	(48,597)	(43,580)	(5,017)

Revenues

We have not generated any revenue during the periods presented. Our ability to generate product revenue and become profitable depends upon our ability to obtain regulatory approval for and to successfully commercialize our product candidates.

Research and Development Expenses

The following table summarizes our research and development expenses during the years ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	Year Ended December 31, 2015	Change
	$'000	$'000	$'000
Clinical development and supporting activities	14,982	12,697	2,285
Antisense Therapeutics license fee	-	3,899	(3,899)
Compensation and related personnel costs	3,037	1,744	1,293
Travel, entertainment and other costs	202	162	40
Preclinical development	1,201	840	361
Stock-based compensation expense	601	793	(192)
Total research and development expenses	20,023	20,135	(112)

Commitments to Taro Pharmaceuticals Industries Ltd are disclosed in note 11 (c) to the consolidated financial statements.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

RESULTS AND DIVIDENDS (CONTINUED)

Research and development expenses were $20.0 million for the year ended December 31, 2016, a $0.1 million decrease compared to the year ended December 31, 2015. The $2.3 million increase in clinical development and supporting activities was primarily attributed to a $3.0 million increase in expense to the ongoing clinical trials for Recorlev, and a $1.4 million increase due to the initiation of the development activity for veldoreotide, partially offset by reduced development spend due to discontinued programs for COR-004 and BioPancreate. Research and development expenses for the year ended December 31, 2015 included $3.9 million of the $5.0 million in aggregate cash paid to Antisense Therapeutics upon entering into a license agreement in May 2015, with the remaining $1.1 million of cash paid recorded as the initial carrying value of our investment in the equity of Antisense Therapeutics. Compensation and related costs increased by $1.3 million, for the year ended December 31, 2016 as compared to the same period in 2015 due to increased headcount of research and development personnel during the 2016 period. Non-cash stock-based compensation decreased $0.2 million due to the departure of certain research and development personnel. Refer to note 3 to notes to the consolidated financial statements.

General and Administrative Expenses

The following table summarizes our general and administrative expenses during the years ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	Year Ended December 31, 2015	Change
	$'000	$'000	$'000
Outside professional services	5,626	8,054	(2,428)
Re-domiciliation and IPO preparation costs	-	4,007	(4,007)
Corporate development and licensing transaction costs	-	3,390	(3,390)
Compensation and related personnel costs	4,555	3,305	1,250
Travel, entertainment and other costs	334	478	(144)
Stock-based compensation expense	4,005	3,147	858
Facility costs	355	338	17
Total general and administrative expenses	14,875	22,719	(7,844)

General and administrative expenses were $14.9 million for the year ended December 31, 2016, a decrease of $7.8 million compared to the year ended December 31, 2015. The $2.4 million decrease in outside professional and consulting services was primarily due to decreased legal fees in support of general corporate matters, employee recruiting fees, and consulting fees for general business efforts. General and administrative expenses for the year ended December 31, 2015 also included $4.0 million of legal and accounting fees related to the redomiciliation of the Company from Sweden to Ireland and the indirect activities necessary to prepare the Company's financial records for the U.S. initial public offering completed in October 2015. General and administrative expenses for the year ended December 31, 2015 also included $3.4 million of transaction fees and expenses related to the acquisition of veldoreotide from Aspireo Pharmaceuticals, the license of COR-004 from Antisense Therapeutics, and other business development activities. Compensation and related personnel costs increased by $1.25 million, travel, entertainment and other costs decreased by $0.15 million and non-cash stock-based compensation by $0.9 million, during the year ended December 31, 2016 due to increased headcount of administrative personnel during the 2016 period.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

RESULTS AND DIVIDENDS (CONTINUED)

Other Income (Expense), Net

The following table summarizes our other income (expense), net, during the years ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	Year Ended December 31, 2015	Change
	$'000	$'000	$'000
Foreign exchange loss	(69)	(124)	55
Interest expense	(20)	-	(20)
Unrealized gain on fair value of warrants	638	-	638
Loss on termination of license agreement with Antisense Therapeutics	(1,051)	-	(1,051)
Other income	144	28	116
Other expense	(273)	(1,133)	860
Total other income (expense), net	(631)	(1,229)	598

Other income (expense), net, increased for the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decrease in other expense, is mostly due to the impairment of our Antisense investment in 2015 of $.5 million as well loss on our Radnor lease of $.2 million, where as in 2016 we returned the license to Antisense and incurred a loss on termination charge of $1.0 million. We also recorded an unrealized gain on the fair value of our warrants.

Income Tax Benefit

We recorded income tax benefit of $2.6 million for the year ended December 31, 2016 and $0.5 million for the year ended December 31, 2015. For the year ended December 31, 2016, the benefit was primarily due to BioPancreate's write off of intellectual property and certain permanent deductions at the new U.S. entity. Additionally, the new U.S. entity is more likely than not to recognize it's deferred tax assets. In December 31, 2015 the benefit was due to the generation of U.S. state and federal net operating loss carry forwards and federal tax credit carry forwards. The income tax benefit for U.S. state and federal net operating loss carry forwards and the federal tax credit carry forwards has been recognized to the extent it is supported by the deferred tax liabilities recorded in connection with the acquisition of BioPancreate.

Net Loss Attributable to Non-controlling Interest

We recorded a net loss attributable to non-controlling interest of $122,000 for the year ended December 31, 2016. The non-controlling interest results from the 0.418% of Cortendo AB shares not acquired by Strongbridge Biopharma plc pursuant to the exchange offer that expired September 3, 2015. In September 2016, the non-controlling interest was acquired by the Company.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

RESULTS AND DIVIDENDS (CONTINUED)

Liquidity and Capital Resources

Our operations have been financed primarily by net proceeds from the issuance of ordinary shares and the issuance of debt. Our primary uses of capital have been third-party expenses associated with the planning and conduct of clinical trials, costs of process development services and manufacturing of our product candidates, and compensation-related expenses. We expect our funding requirements for operating activities to increase in 2017 and possibly beyond due to expenses associated with the commercialization of Keveyis, the execution of the Phase 3 SONICS and LOGICS clinical trials for Recorlev, and selling, general and administrative expenses. We also expect our cash needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy. These expenses may be offset only in part by sales of Keveyis. In addition, beginning in June 2018, we will be required to make monthly principal payments to repay amounts borrowed under our credit facility.

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We believe that our cash resources will be sufficient to allow us to fund planned operations at least into 2019, which is after the expected receipt of data from the Recorlev SONICS and LOGICS Phase 3 clinical trials.

Our future funding requirements will depend on many factors, including the following:

- the amount of revenue that we receive from sales of Keveyis; the cost and timing of establishing sales, marketing, distribution and administrative capabilities;
- the scope, rate of progress, results and cost of our clinical trials testing and other related activities;
- whether we borrow any additional amounts under our credit facility;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

We expect to continue to incur losses. Our ability to achieve and maintain profitability is dependent upon the successful commercialization of Keveyis, the development, regulatory approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials, funding may not be available to us on acceptable terms, or at all.

We plan to continue to fund our operations and capital funding needs through equity or debt financing, along with revenues from Keveyis. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. In addition, lack of funding would limit any strategic initiatives to in-license or acquire additional product candidates or programs.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

RESULTS AND DIVIDENDS (CONTINUED)

Cash Flows

Comparison for the years ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Net cash (used in) provided by:		
Operating activities	(31,714)	(37,360)
Investing activities	(3,392)	(4,294)
Financing activities	50,320	77,404
	15,214	35,750
Effect of exchange rate changes on cash and cash equivalents	-	241
Net increase in cash and cash equivalents	15,214	35,991

Operating Activities

Net cash used in operating activities was $31.7 million for the year ended December 31, 2016, compared to $37.4 million for the year ended December 31, 2015. The decrease in net cash used was primarily due to business development activities and fees related to indirect activities necessary to redomicile the Company and to prepare the Company's financial records for the U.S. initial public offering that occurred in 2015.

Investing Activities

The $3.4 million of cash used in 2016 investing activities related to the purchase of Keveyis. The $4.3 million of cash used in 2015 investing activities primarily related to the acquisition of veldoreotide and the license of COR-004 in 2015.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2016 was $50.3 million and consisted of $32.7 million of proceeds from the issuance of ordinary shares and warrants in a private placement financing and $19.3 million proceeds from the issuance of debt and warrants. Net cash provided by financing activities for the year ended December 31, 2015 was $77.4 million, which consisted of proceeds from the issuance of ordinary shares in private placement financings and our IPO in October of 2015.

AUDIT COMMITTEE

In accordance with Section 167 of Companies Act 2014, the Company has established an audit committee for the full financial year.

The current members of our audit committee are, Richard Kollender, Hilde Steineger and Jeffrey Sherman, with Mr. Kollender serving as chairman. Our board of directors has determined that each member of our audit committee is independent under Rule 10A-3 of the Exchange Act and the applicable listing requirements of NASDAQ, and that each member of our audit committee satisfies the other listing requirements of NASDAQ for audit committee membership. Our board of directors has also determined that two of the three members of our audit committee, Mr. Kollender and Dr. Steineger, qualify as an "audit committee financial expert," as such term is defined by the SEC, and that he or she has the requisite level of financial sophistication required by the continued listing standards of NASDAQ.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

DIRECTORS AND COMPANY SECRETARIES

The directors and the company secretary who served during the year are listed on page 2. No director, secretary or any member of their immediate families had any interest in shares or debentures of any subsidiary. Directors' remuneration is set forth in note 22 of the Consolidated Financial Statements.

The interest of the directors in ordinary share capital of the Company at December 31, 2016 and December 31, 2015 (or date of appointment if later) are as follows:

	2016			2015		
Name	Ordinary shares No of shares	Stock Options No of shares	Restricted Stock Units No of shares	Ordinary shares No of shares	Stock Options No of shares	Restricted Stock Units No of shares
John Johnson	-	107,767	-	-	67,767	-
Richard Kollender	-	77,188	-	-	37,188	-
Garheng Kong	-	74,385	-	-	34,385	-
Mårten Steen	-	74,918	-	-	34,918	-
Hilde H. Steineger	-	74,918	-	-	34,918	-
Jeffrey Sherman (appointed October 1, 2016)	-	60,000	-	-	-	-
Matthew Pauls	4,215	906,817	40,000	4,215	681,817	-

The Company Secretary held ordinary shares of 1,718 as at December 31, 2016 (2015: 1,718) and at date of appointment. Stock options held by the Company Secretary amounted to 251,908 as at December 31, 2016 (2015: 187,908).

DIRECTORS' COMPLIANCE STATEMENT

The directors, in accordance with Section 225(2) (a) of the Companies Act 2014, acknowledge that they are responsible for securing the Company's compliance with its "relevant obligations" (as defined in the Companies Act 2014).

Pursuant to Section 225(2) (b) of the Companies Act 2014, the directors confirm that:

(i) a compliance policy statement has been drawn up as required by Section 225(3) (a) of the Companies Act 2014 setting out the Company's policies (that, in the directors' opinion, are appropriate to the Company) respecting compliance by the Company with its relevant obligations;
(ii) appropriate arrangements and structures have been put in place that, in their opinion, secure material compliance with the Company's relevant obligations, and
(iii) a review has been conducted, in the year ended December 31, 2016, of the arrangements and structures referred to in paragraph (ii).

In discharging their responsibilities under Section 225 of the Companies Act 2014, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise the Company on compliance with its relevant obligations.

DISCLOSURE OF INFORMATION TO AUDITORS

So far as each of the directors in office at the date of approval of the financial statements is aware:

- There is no relevant audit information of which the Company's auditors are unaware; and
- The directors have taken all the steps that they ought to have taken as directors in order to make themselves aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Companies Act 2014.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

RELATED PARTY DISCLOSURES

On December 22, 2016, we entered into a Share Purchase Agreement to sell $35 million of our shares in a private placement (14,000,000 shares at a subscription price of $2.50 per share). Certain of our existing 5% shareholders that beneficially own more than 5% of our ordinary shares and/or their affiliates purchased ordinary shares in this transaction, including New Enterprise Associates, Broadfin, Eigil Stray Spetalen and HealthCap VI, LP, of which Dr. Steen, one of our directors, is a partner.

There were no other contracts of any significance in relation to the business of the Company in which the directors had any interest, as defined in the Companies Act 2014, at any time during the year.

POWERS OF DIRECTORS

The Board is responsible for managing the business affairs of the Company in accordance with the Constitution of the Company, which allow them to enter into contracts and perform all tasks necessary to conduct the business of the Company. The Board may delegate certain functions to other parties, subject to supervision and direction by the directors. The Board consists of seven directors (2015: six).

SHAREHOLDER MEETINGS

The shareholders' rights and operations of shareholders meetings are defined in the Constitution and comply with the Companies Act 2014. The Company will hold a general meeting each year as its annual general meeting in addition to any other meeting in that year. The annual general meeting date and agenda is specified in the notice sent out for the meeting.

FINANCIAL RISK MANAGEMENT

The operations of the Company are subject to various risks. Information about the capital and financial risk management objectives and policies of the Company, along with exposure of the Company to the relevant financial risks, are disclosed on pages 5 to 42 of this report and in note 15 to the consolidated financial statements.

POLITICAL DONATIONS

No political contributions that require disclosure under Irish law were made during the year (2015: nil).

DIVIDENDS

No dividends were proposed or paid in either 2015 or 2016.

FUTURE DEVELOPMENTS

The Company will continue to focus on developing treatments for rare diseases. We are preparing to independently commercialize Keveyis in the United States and intend to do likewise with our two rare disease product candidates, if approved, in the United States, the European Union, and, selectively, in other key global markets. We intend to expand our portfolio through a disciplined in-licensing and acquisition strategy. We intend to build our company by in-licensing and acquiring products and product candidates that target rare diseases in therapeutically aligned franchises with significant commercial opportunity. We believe that complementary products and product candidates will allow us to significantly leverage our expertise as well as our development and commercial infrastructure. For example, Keveyis serves as the basis of our rare neuromuscular franchise, and our product candidates for the treatment of endogenous Cushing's syndrome and acromegaly, if approved, will serve as the basis for our rare endocrine franchise. In addition to identifying products and product candidates that can form the basis of new rare disease franchises, we also intend to leverage opportunities to develop potential products and product candidates for additional indications within their respective therapeutic franchises.

DIRECTORS' REPORT (CONTINUED)
FOR THE YEAR ENDED DECEMBER 31, 2016

GOING CONCERN

The directors' have evaluated the relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they have chosen to adopt the going concern basis in preparing the financial statements.

SIGNIFICANT SUBSEQUENT EVENTS

On March 31, 2017 we entered into an amendment to the Loan Agreement that was made effective as of January 27, 2017 and provided for an extension to the dates by which the Company's Swedish subsidiary was required to enter into security documents granting security interests on certain of its assets in favor of Oxford, as collateral agent for the Lender, and to increase the amount of debt the Company can incur under, and the amount of cash collateral it can provide for purposes of, its corporate credit card program from $100,000 to $250,000. In connection with the amendment, the Company paid $150,000 to the Lenders.

There were no other significant subsequent events after the year-end until the date of approval of these financial statements that would require adjustment to or disclosure in the financial statements. Key subsequent events arising are disclosed in note 11 of the consolidated financial statements.

ACCOUNTING RECORDS

The directors are responsible for ensuring that adequate accounting records, as outlined in Section 281 to 285 of the Companies Act 2014, are kept by the Company and its subsidiaries. The measures taken by directors to ensure compliance with the Company's obligation to keep adequate accounting records are the use of appropriate systems and procedures and by ensuring that a competent service provider is responsible for the preparation and maintenance of the accounting records. The accounting records of the Company are kept at 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, Ireland.

INDEPENDENT AUDITOR

Ernst & Young, Chartered Accountants, have expressed their willingness to continue in office in accordance with Section 383(2) of the Companies Act 2014.

The report was approved on 11 April 2017 by the Board and authorised for issue by:

/s/ Matthew Pauls
Matthew Pauls
Director

/s/ Richard Kollender
Richard Kollender
Director

STATEMENT OF DIRECTORS' RESPONSIBILITIES

Company law in Ireland requires the directors to prepare financial statements for each financial year which give a true and fair view of the state of the assets, liabilities and financial position of the Parent Company and of the Group and of the profit or loss of the Group for that period.

In preparing the financial statements of the Group, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- comply with applicable US generally accepted accounting principles to the extent that the use of US generally accepted accounting principles does not contravene any provision of the Companies Act 2014, subject to any material departures disclosed and explained in the financial statements; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group will continue in business

The considerations set out above for the Group are also required to be addressed by the Directors in preparing the financial statements of the Parent Company (which are set out on pages 83 to 93), in respect of which the applicable accounting standards are those which are generally accepted in Ireland.

The directors have elected to prepare the Parent Company's financial statements in accordance with accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland, including FRS 102 The Financial Reporting Standard applicable in the UK and Republic of Ireland (Generally Accepted Accounting Practice in Ireland).

Under company law the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position, of the group and parent company as at the end of the financial year, and the profit or loss for the group for the financial year, and otherwise comply with the Companies Act 2014.

The Directors are responsible for keeping adequate accounting records which correctly record and explain the transactions of the Company; enable at any time the assets, liabilities, financial position and profit and loss of the Parent Company to be determined with reasonable accuracy; enable them to ensure that the financial statements of the Group are prepared in accordance with applicable US generally accepted accounting principles and comply with the provisions of the Companies Act 2014; and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The report was approved on 11 April 2017 by the Board and authorised for issue by:

/s/ Matthew Pauls
Matthew Pauls
Director

/s/ Richard Kollender
Richard Kollender
Director

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF STRONGBRIDGE BIOPHARMA PLC

We have audited the financial statements of Strongbridge Biopharma plc for the year ended 31 December 2016 which comprise the Consolidated Profit and Loss Account, the Consolidated Balance Sheet, the Consolidated Statement of Cash Flows, the Consolidated Statement of Changes in Equity, the Parent Company Balance Sheet, the Parent Company Statement of Changes in Equity, the related notes 1 to 26 in respect of the group financial statements and the related notes 1 to 16 in respect to the parent company financial statements. The financial reporting framework that has been applied in the preparation of the group financial statements is Irish law and U.S. Generally Accepted Accounting Principles (U.S. GAAP), as defined in section 279 of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of that Part of the Companies Act 2014 and for the preparation of the parent company financial statements in accordance with Irish law and accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland, including FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (Generally Accepted Accounting Practice in Ireland).

This report is made solely to the company's members, as a body, in accordance with section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Respective responsibilities of directors and auditors

As explained more fully in the Statement of Directors' Responsibilities set out on page 51, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014. Our responsibility is to audit the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). These standards require us to comply with the Auditing Practices Board's (APB's) Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the group's and parent company's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the directors; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information in the directors' report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect or materially inconsistent with the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

INDEPENDENT AUDITOR'S REPORT (CONTINUED)

Opinion on financial statements

In our opinion:

- the group financial statements give a true and fair view in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP), as defined in section 279 of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of that Part of the Companies Act 2014, of the assets, liabilities and financial position of the Group as at 31 December 2016 and of the loss for the Group for the year then ended;
- the parent company statement of financial position gives a true and fair view of the assets, liabilities and financial position of the parent company as at 31 December 2016 and has been properly prepared in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland*; and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

Matters on which we are required to report by the Companies Act 2014

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the parent company financial statements to be readily and properly audited.
- The parent company balance sheet is in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements.

Matters on which we are required to report by exception

We have nothing to report in respect of Sections 305 to 312 of the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

/s/ Breffni Maguire

Breffni Maguire
For and on behalf of Ernst & Young
Chartered Accountants and Statutory Audit Firm
Dublin

11 April 2017

CONSOLIDATED PROFIT AND LOSS ACCOUNT

	Notes	Year Ended December 31, 2016 $'000	Year Ended December 31, 2015 $'000
Operating expenses			
Research and development	3	(20,023)	(20,135)
General and administrative	4	(14,875)	(22,719)
Impairment of intangible assets	8	(15,828)	-
Total operating expenses		(50,726)	(42,854)
Operating loss		(50,726)	(42,854)
Other (expense) net:			
Foreign exchange loss		(69)	(124)
Unrealized gain on fair value of warrants		638	-
Interest expense		(20)	-
Loss on termination of license agreement with Antisense Therapeutics		(1,051)	-
Other income	5	144	28
Other expense	5	(273)	(1,133)
Total other (expense) net		(631)	(1,229)
Loss before taxes		(51,357)	(44,083)
Tax benefit	18	2,638	450
Net loss		(48,719)	(43,633)
Net loss attributable to non-controlling interest		122	53
Net loss attributable to ordinary shareholders of the Company		(48,597)	(43,580)
Net loss attributable to ordinary shareholders:			
Basic		(48,597)	(43,580)
Diluted		(49,236)	(43,580)
Net loss per share attributable to ordinary shareholders:			
Basic		(2.26)	(2.62)
Diluted		(2.27)	(2.62)
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:			
Basic		21,550,353	16,606,669
Diluted		21,655,564	16,606,669

The accompanying notes are an integral part of the Consolidated Financial Statements.

CONSOLIDATED BALANCE SHEET

	Notes	As at December 31, 2016 $'000	As at December 31, 2015 $'000
ASSETS			
Fixed assets			
Tangible assets - Property and equipment, net	7	25	35
Intangible assets - In-process research and development	8	60,900	36,551
Intangible Assets - Goodwill	8	7,256	7,256
Investments and other assets	9	150	612
Deferred tax assets		1,599	-
Current assets			
Debtors (falling due within one year)		764	1,253
Cash at bank and in hand	6	66,837	51,623
Total assets		137,531	97,330
LIABILITIES AND SHAREHOLDERS' EQUITY			
Shareholders' equity			
Share capital	17	397	256
Share premium		188,970	165,719
Other reserves		7,005	5,191
Profit and loss account		(129,400)	(80,803)
Attributable to Shareholders in the Company		66,972	90,363
Non-controlling interest		-	564
Total Shareholders' equity		66,972	90,927
Provisions for liabilities			
Warrant liabilities	13	11,090	-
Deferred tax liabilities	18	-	926
Creditors – amounts falling due within one year			
Accounts payable		1,089	2,792
Accrued liabilities	10	14,868	2,685
Creditors – amounts falling due after more than one year			
Long term debt	12	18,434	-
Long term accrued liabilities	14	25,078	-
Total liabilities		70,559	6,403
Total liabilities and Shareholders' equity		137,531	97,330

The accompanying notes are an integral part of the Consolidated Financial Statements.

The Consolidated Financial Statements were approved and signed on behalf of the Board of Directors on 11 April 2017:

/s/ Matthew Pauls
Matthew Pauls
Director

/s/ Richard Kollender
Richard Kollender
Director

CONSOLIDATED STATEMENT OF CASH FLOWS

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Cash flows from Operating Activities		
Net loss	(48,719)	(43,633)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	11
Stock-based compensation	4,606	3,940
Deferred income tax benefit	(2,638)	(450)
Impairment of intangibles assets	15,828	-
Impairment on investment in Antisense Therapeutics	-	551
Loss on termination of license agreement with Antisense Therapeutics	550	-
Change in fair value of warrant liability	(638)	-
Change in fair value of foreign currency forward contracts	-	438
Changes in working capital:		
- Accounts payable	(1,702)	1,737
- Accrued liabilities	475	1,263
- Other assets	(88)	(52)
- Prepaid expenses and other current assets	602	(1,165)
Net cash used in operating activities	(31,714)	(37,360)
Cash flows from Investing Activities		
Payments for acquisitions	(3,392)	(3,168)
Investment in Antisense Therapeutics	-	(1,101)
Purchase of equipment	-	(25)
Net cash used in investing activities	(3,392)	(4,294)
Cash flows from Financing Activities		
Proceeds from Initial Public Offering, net	-	19,475
Proceeds from issuance of ordinary shares	32,298	58,341
Proceeds from exercise of stock options	120	-
Proceeds from Loan Agreement, net	19,316	
U.S. non-accredited shares repurchased	(1,414)	(412)
Net cash provided by financing activities	50,320	77,404
Effect of exchange rate changes on cash and cash equivalents	-	241
Net increase in cash and cash equivalents	15,214	35,991
Cash and cash equivalents—beginning of period	51,623	15,632
Cash and cash equivalents—end of period	66,837	51,623

The accompanying notes are an integral part of the Consolidated Financial Statements.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
(In thousands except share amounts)

	Called up Share Capital Shares	Called up Share Capital Amount	Share Premium	Other Reserves	Profit and Loss Account	Non-controlling Interest	Total Equity
		$'000	$'000	$'000	$'000	$'000	$'000
Balance at January 1, 2016	21,245,382	256	165,719	5,191	(80,803)	564	90,927
Net loss	-	-	-	-	(48,597)	(122)	(48,719)
Stock-based compensation	-	-	-	4,606	-	-	4,606
Acquisition of non-controlling interest	-	-	-	(972)	-	(442)	(1,414)
Issuance of shares, net of fair value of warrants granted	14,000,000	140	23,132	-	-	-	23,272
Costs on issuance of shares	-	-	-	(2,345)	-		(2,345)
Exercise of stock options	129,644	1	119	-	-	-	120
Issuance of warrants related to the loan agreement	-	-	-	525	-	-	525
Balance at December 31, 2016	35,375,026	397	188,970	7,005	(129,400)	-	66,972

	Called up Share Capital Shares	Called up Share Capital Amount	Share Premium	Other Reserves	Profit and Loss Account	Non-controlling Interest	Total Equity
		$'000	$'000	$'000	$'000	$'000	$'000
Balance at January 1, 2015	9,700,789	97	55,467	480	(37,223)	-	18,821
Net loss	-	-	-	-	(43,580)	(53)	(43,633)
Stock-based compensation	-	-	-	3,581	-	-	3,581
Reclassification of stock-based liability award to equity	-	-	-	1,542	-	-	1,542
Issuance of Shares	9,108,169	91	91,418	-	-	-	91,509
US Non Accredited Shares Repurchased	(24,955)	-	-	(412)	-	-	(412)
Issuance of shares in initial public offering, net	2,500,000	25	19,450	-	-	-	19,475
Non-controlling interest resulting from exchange offer	(78,621)	(1)	(616)	-	-	617	-
Euro Beneficial shares issued	40,000	44	-	-	-	-	44
Balance at December 31, 2015	21,245,382	256	165,719	5,191	(80,803)	564	90,927

The accompanying notes are an integral part of the Consolidated Financial Statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. GENERAL INFORMATION

The Company was incorporated under the laws of Ireland on May 26, 2015 with registered number 562659 as a public limited company under the Companies Act 2014 and is domiciled in Ireland.

The Company is a biopharmaceutical entity focused on the development, in-licensing, acquisition and eventual commercialisation of multiple complementary products and product candidates within franchises that target rare diseases.

The consolidated financial statements of the Company have been prepared in accordance with Section 279 of Part 6 of the Companies Act 2014, which provides that a true and fair view of the state of affairs and profit or loss may be given by preparing the financial statements in accordance with generally accepted accounting principles in the United States (U.S. GAAP), as defined in Section 279(1) of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the consolidated financial statements does not contravene any provision of that part of the Companies Act 2014.

These consolidated financial statements were prepared in accordance with Irish Company Law, to present to the shareholders of the Company and file with the Companies Registration Office in Ireland. Accordingly, these consolidated financial statements include presentation and additional disclosures required by Ireland's Companies Act 2014 in addition to those disclosures required under U.S. GAAP.

Terminology typically utilised in a set of U.S. GAAP financial statements has been retained for the benefit of those users of these financial statements who also have access to our form 20-F U.S. GAAP financial statements, rather than defaulting to the terminology set out under Irish Company Law. Accordingly, references to other income, other expense, tax benefit and net loss have the same meaning as references to other interest receivable and similar income, interest payable and similar charges, tax on profit or loss on ordinary activities, loss on ordinary activities after taxation under Irish Company Law.

The consolidated financial statements include the accounts of the Company, BioPancreate Inc. (Trevose, Pennsylvania, United States), Cortendo AB (Gothenburg, Sweden), Cortendo Cayman Ltd (Georgetown, Cayman Islands) and Strongbridge U.S. Inc. (Delaware, United States). All intercompany transactions and balances have been eliminated in consolidation.

The preparation of consolidated financial statements requires management to make estimates and assumptions, which affect the reported earnings, financial position and various disclosures. Although the estimates are considered reasonable, actual results could differ from the estimates.

The Company's functional currency is United States Dollars (USD). Transactions in foreign currencies are translated into the functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange loss in the consolidated statement of comprehensive income.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. Reconciliation to amounts reported in the Company's annual report on Form 20-F filed with the United States Securities and Exchange Commission ("the U.S. SEC")

These consolidated financial statements are prepared using U.S. GAAP to the extent that the use of such principles does not contravene Irish Company Law. The consolidated financial statements included in the annual report on Form 20-F as filed on March 24, 2016 with the U.S. SEC are prepared using U.S. GAAP. The primary differences between these statutory financial statements and the Consolidated Financial Statements included on Form 20-F is the presentation format of the income statement and balance sheet and the inclusion of certain additional disclosures.

It is noted that there are no material differences to be reconciled between the two financial statements.

b. Cash at bank and in hand

Cash and cash equivalents consist of account balances at banks and money market accounts, respectively. We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. The carrying amount of cash approximates its fair value.

c. Fixed Assets

Property and equipment, net, consists of computer and related IT equipment. Computers and related IT equipment are depreciated over their useful life of 2 to 5 years. Depreciation expense for the years ended December 31, 2016 and 2015 was not significant.

d. Goodwill

Irish Company law requires that goodwill is written off over a period of time which does not exceed its useful economic life. However, the Company does not believe this gives a true and fair view as not all goodwill and intangible assets decline in value. In addition, since goodwill that does decline in value rarely does so on a straight-line basis, straight-line amortization of goodwill over an arbitrary period does not reflect the economic reality. Consistent with U.S. GAAP, Strongbridge considers goodwill an indefinite-lived intangible asset that is not amortized over an arbitrary period. Rather, the Company accounts for goodwill in accordance with US GAAP. Therefore in order to present a true and fair view of the economic reality, goodwill is considered indefinite-lived and is not amortized. The Company is not able to reliably estimate the impact on the financial statements of the true and fair override on the basis that the useful economic of goodwill cannot be predicted with a satisfactory level of reliability nor can the pattern in which goodwill diminishes be known.

Goodwill represents the cost of acquired companies in excess of the fair value of the net assets of such companies at the acquisition date. Goodwill is tested for impairment annually in the Company's fourth quarter, or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The test for impairment requires the Company to make several estimates about fair value, most of which are based on projected future cash flows and market valuation multiples. The estimates associated with the goodwill impairment tests are considered critical due to the judgments required in determining fair value amounts, including projected discounted future cash flows. Changes in these estimates may result in the recognition of an impairment loss.

The Group test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

e. Goodwill (continued)

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

To estimate the fair value of the business, primarily a market-based approach is applied, utilizing our public market value. We did not record a charge for impairment for the years ended December 31, 2015 and 2016.

f. In-process research and development

Purchased identifiable intangible assets with indefinite lives, such as our in-process research and development, are evaluated for impairment annually in accordance with our policy and whenever events or changes in circumstances indicate that it is more likely than not that the fair value of these assets may not be recovered.

To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach. For the impairment analysis for the year ended December 31, 2016, significant unobservable inputs used in the income approach valuation method including a discount rates, royalty rates and probabilities of product candidate advancement from one clinical trial phase to the next. The determination of fair value of indefinite lived assets is considered Level 3 for fair value measurement.

g. Share-Based Awards

We account for stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values.

Our stock-based awards are subject to either service-based or performance-based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market-based vesting conditions. Certain awards also contain a combination of service and market conditions or performance and market conditions.

We account for employee stock-based awards at grant-date fair value. If we issue awards with an exercise price denominated in a currency other than our functional currency, trading currency or the currency for which we compensate our employee, we account for these as liabilities. We account for non-employee and liability-classified stock-based awards based on the then-current fair values at each financial reporting date until the performance is complete for non-employee awards, or until the award is settled (exercised) for liability-classified awards. Changes in the amounts attributed to these awards between the reporting dates are included in stock-based compensation expense (credit) in our statements of operations. We include liability-classified stock options in non-current liabilities in our balance sheets as their settlement (exercise) does not require use of cash, cash equivalents or other current assets.

We record compensation expense for service-based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. For those awards in which the performance condition was the completion of our IPO, we did not recognize compensation expense until the close of the IPO as we did not deem the IPO probable until it occurred.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

g. Share-Based Awards (continued)

Compensation expense for awards with service and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market-based vesting provisions.

We estimate the fair value of our awards with service conditions using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of historical and implied volatility data of our common stock, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. We compute historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

We estimate the fair value of our awards with market conditions using a Monte Carlo simulation to determine the probability of satisfying the market condition. We make this estimate using the conditions that exist at the grant date. The derived service period, which may be the requisite service period, is also determined at this time. Compensation cost for our awards with a market condition is recognized ratably using the accelerated attribution method if the award is subject to graded vesting over the requisite service period. The compensation cost for our awards with a market condition is not reversed if the market condition is not satisfied.

We have estimated the expected term of employee service-based stock options using the "simplified" method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with market conditions using a Monte-Carlo simulation model. This approach involves generating random stock-price paths through a lattice-type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service- and performance-based awards based on the remaining contractual term of such awards.

The risk-free interest rates for periods within the expected term of the option are based on the Swedish Government Bond rate or the U.S. Treasury Bond rate with a maturity date commensurate with the expected term of the associated award. We have never paid dividends, and do not expect to pay dividends in the foreseeable future.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from estimates. We record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised.

h. Taxes

We use the asset and liability method of accounting for income taxes in accordance with FASB ASC Topic 740, Income Taxes (ASC 740). Under this method, income tax expense is recognized for the amount of (1) taxes payable or refundable for the current year and (2) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

h. Taxes (continued)

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC 740 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We have no material uncertain tax positions for any of the reporting periods presented.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2015 and 2016, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our statements of operations.

i. Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include compensation and related expenses. External expenses include development, clinical trials, report writing and regulatory compliance costs incurred with clinical research organizations and other third-party vendors. At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. Upfront and milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered.

j. Earnings per Share ("EPS")

Basic EPS is calculated using the weighted average number of shares of common stock outstanding during each period. It excludes both the dilutive effects of additional common shares that would have been outstanding if the shares issued under stock incentive plans had been exercised and the dilutive effects of restricted shares and restricted share units, to the extent those shares and units have not vested. Diluted EPS is calculated including the effects of shares and potential shares issued under stock incentive plans, following the treasury stock method.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

3. RESEARCH AND DEVELOPMENT

The Group incurred research and development expenses of $20.0 million and $20.1 million for the years ended December 31, 2016 and 2015, respectively as summarised as follows:

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	**$'000**
Clinical development and supporting activities	14,982	12,697
Antisense Therapeutics license fee	-	3,899
Compensation and related personnel costs	3,037	1,744
Travel, entertainment and other costs	202	162
Preclinical development	1,201	840
Stock-based compensation expense	601	793
Total research and development expenses	20,023	20,135

4. GENERAL AND ADMINISTRATION

General and administration expenses for the years ended December 31, 2016 and 2015 are summarised as follows (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	**$'000**
Outside professional services	5,626	8,054
Re-domiciliation and IPO preparation costs	-	4,007
Corporate development and licensing transaction costs	-	3,390
Compensation and related personnel costs	4,555	3,305
Travel, entertainment and other costs	334	478
Stock-based compensation expense	4,005	3,147
Facility costs	355	338
Total general and administrative expenses	14,875	22,719

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. OTHER INCOME AND OTHER EXPENSE

Other income for the years ended December 31, 2016 and 2015 are summarised as follows (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Interest income	1	25
Dividend income	143	3
Total other income	144	28

Other expense for the years ended December 31, 2016 and 2015 are summarised as follows (in thousands):

	Year Ended December 31, 2016 $'000	Year Ended December 31, 2015 $'000
Impairment loss on Antisense Therapeutics	-	(550)
Loss on investment	(266)	-
Realised (loss)/gain on financial derivatives	-	(438)
Lease expense	(7)	(141)
Interest expense	-	(3)
Other expense	-	(1)
Total other expense	(273)	(1,133)

6. CASH AND CASH EQUIVALENTS

Cash at bank and in hand includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturity of three months or less. The total amount of cash and cash equivalents held at 31 December 2016 in thousands was $66,837 (2015: $51,623).

7. PROPERTY AND EQUIPMENT, NET

Property and equipment, net relates to computers and related IT equipment can be summarized as follows:

	Year Ended December 31, 2016		Year Ended December 31, 2015	
	Computer & related IT Equipment $'000	Total $'000	Computer & related IT Equipment $'000	Total $'000
Cost				
At beginning of the year	137	137	112	112
Additions	-	-	25	25
At end of the year	137	137	137	137
Accumulated depreciation				
At beginning of the year	(102)	(102)	(91)	(91)
Depreciation charge for the year	(10)	(10)	(11)	(11)
At end of the year	(112)	(112)	(102)	(102)
Net Book Value				
At beginning of the year	35	35	21	21
At end of the year	25	25	35	35

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

8. GOODWILL AND IN-PROCESS RESEARCH AND DEVELOPMENT

The following table presents in-process research and development and goodwill as of and during the years ended December 31, 2016 and December 31, 2015 (in thousands):

	As of December 31, 2016				
	Opening	**Additions**	**Disposals**	**Impairment**	**Closing**
	$'000	**$'000**	**$'000**	**$'000**	**$'000**
In-process research and development	36,551	-	-	(15,828)	20,723
Acquired product rights	-	40,177	-	-	40,177
Total	36,551	40,177	-	(15,828)	60,900
Goodwill	7,256	-	-	-	7,256

	As of December 31, 2015				
	Cost	**Additions**	**Disposals**	**Impairment**	**Closing**
	$'000	**$'000**	**$'000**	**$'000**	**$'000**
In-process research and development	5,228	31,323		-	36,551
Total	5,228	31,323		-	36,551
Goodwill	2,200	5,056		-	7,256

Goodwill and in-process research and development as of December 31, 2015 and 2016 resulted from our acquisition of BioPancreate and our 2015 acquisition of veldoreotide (formerly called COR-005) from Aspireo Pharmaceuticals, Ltd.

In-process research and development is initially measured at its fair value and is not amortized until commercialization. Once commercialization occurs, in-process research and development will be amortized over its estimated useful life.

We recorded $5.2 million of impairment relating to our Biopancreate IPR&D and $10.6 million impairment for our veldoreotide IPR&D for the year ended December 31, 2016 (2015: nil).

Our finite lived intangible asset consist of acquired developed product rights obtained from the asset acquisition of Keveyis® (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. ("Taro"). Keveyis is approved in the U.S. to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Keveyis has received orphan drug exclusivity status in the U.S through August 7, 2022. In connection with the Asset Purchase and Supply Agreement we entered into with Taro Pharmaceutical Industries Ltd, we have paid Taro an upfront payment in two installments of $1 million in December 2016 and $7.5 million in March 2017. We have concluded that the supply price payable by us exceeds fair value and, therefore, have used a discounted cash flow method with a probability assumption to value the payments in excess of fair value at $29.3 million, for which we have recorded an intangible asset and corresponding liability. This liability will be amortized as we purchase inventory over the term of the agreement. In addition, we incurred transaction costs of $2.4 million resulting in the recording of an Intangible Asset of $40.2 million. This asset will be amortized as units are sold over an estimated 8 year period.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. INVESTMENTS AND OTHER ASSETS

Other assets as at year ended December 31, 2016 and December 31, 2015 relate to following (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Antisense Stock Investment*	-	550
Deposits on leased facilities	50	62
Other	100	-
Total	150	612

*In April 2016, we executed an agreement (the "Settlement Agreement") with Antisense Therapeutics ("Antisense") to terminate the exclusive license agreement (the "Antisense License Agreement") that we and Antisense entered into in May 2015. See note 11 for further information in this regard and costs associated.

10. ACCRUED LIABILITIES

Accrued liabilities as at year ended December 31, 2016 and December 31, 2015 consist of the following (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Consulting and professional fees	1,110	1,288
Employee compensation	1,554	1,172
Payable to Taro	7,500	-
Payroll liabilities	-	-
Income tax liability	243	-
Other	4,461	225
Total	14,868	2,685

11. COMMITMENTS AND CONTINGENCIES

(a) Lease

On April 22, 2014, we entered into a 48-month building lease for approximately 3,000 square feet of space in Radnor, Pennsylvania. The lease has annual rent escalations. We obtained access to the newly leased space on August 1, 2014, and this was considered the lease commencement date for accounting purposes. Thus, rent expense began on this date and is recognized on a straight-line basis over the term of the lease.

In March 2015, the Company entered into a 52-month building sublease agreement for 14,743 square feet of office space in Trevose, Pennsylvania. The lease has annual rent escalations and is recognized on a straight-line basis over the term of the lease. As a result of this lease, we vacated the previously leased Radnor, Pennsylvania facility as of April 13, 2015 and determined that the Radnor, Pennsylvania facility was not likely to be utilized during the remaining lease term and as such we commenced efforts to sublease the facility. The Company recorded a liability as of the April 13, 2015 cease-use date of $0.1 million for the estimated fair value of its obligations under the lease. The most significant assumptions used in determining the amount of the estimated liability are the potential sublease revenues and the credit-adjusted risk-free rate utilized to discount the estimated future cash flows.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(a) Lease (continued)

As of December 31, 2016 and 2015, future minimum commitments under facility operating leases were as follows:

	As at December 31, 2016	As at December 31, 2015
	$'000	$'000
2016	-	227
2017	311	311
2018	319	319
2019	184	184
Total minimum lease payments	814	1,041

Rent expense recognised under the operating lease, including additional rent charges for utilities, parking, maintenance and real estate taxes, for the year ended 31 December 2016 amounted to (in thousands) $275 (2015: $254).

(b) License Agreements

Cornell Center for Technology Enterprise and Commercialization

In 2011, a license agreement was executed between BioPancreate and the Cornell Center for Technology Enterprise and Commercialization (CCTEC). Under the terms of the license agreement, BioPancreate obtained certain rights from the CCTEC for commercial development, use and sale of products that use the technology associated with the license. We are obligated to make milestone payments upon the achievement of certain regulatory and clinical milestones up to $2.6 million in the aggregate. For years in which licensed products are sold, we are required to pay a royalty based on a low single-digit percentage of net sales. The minimum annual royalty in such years is $100,000. In the event the product is sublicensed, up to $3.5 million of certain fees we receive that are not earned royalties or reimbursements for direct costs are due to CCTEC upon achievement of certain regulatory and clinical milestones.

In October 2016, our wholly owned subsidiary, BioPancreate Inc., provided a notice to Cornell University, through its Cornell Center for Technology Enterprise and Commercialization ("CCTEC"), in accordance with the terms of its agreement with CCTEC entered into in March 2011, of the termination of the agreement. The notice was provided in accordance with our decision to terminate our development program for BP-2002, a gene-modified probiotic in pre-clinical development for the potential treatment of type 1 and 2 diabetes that was the subject of the agreement. We recorded an impairment charge of $5.2 million during the year ended December 31, 2016, which represented the value of the intangible asset we had previously capitalized related to the license agreement.

Antisense Therapeutics

In May 2015, we entered into an exclusive license agreement, or the Antisense License Agreement, with Antisense Therapeutics that provided us with development and commercialization rights to Antisense Therapeutics' product candidate, ATL1103, for endocrinology applications (specifically excluding the treatment of any form of cancer and the treatment of any complications of diabetes). We refer to this product candidate as COR-004. Under the terms of the Antisense License Agreement, we paid Antisense Therapeutics an initial upfront license fee of $3.0 million in cash which was recorded as research and development expenses. We also invested $2.0 million in Antisense Therapeutics equity which was initially recorded as a non-current other asset for $1.1 million with the difference constituting the cost of the license which was recorded as research and development expense. The terms of the Antisense License Agreement provided that we could terminate the Antisense License Agreement upon 90 days' prior written notice to Antisense Therapeutics if we believed the further development and commercialization of COR-004 was no longer feasible due to a material change that was beyond our control. If, however, it is determined that we terminated the Antisense License Agreement for convenience, we would be required to pay Antisense Therapeutics a $2.0 million termination fee.

11. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(b) License Agreements (continued)

In April 2016, we executed an agreement (the "Settlement Agreement") with Antisense Therapeutics ("Antisense") to terminate the exclusive license agreement (the "Antisense License Agreement") that we and Antisense entered into in May 2015. Pursuant to the terms of the Settlement Agreement, we have made a one-time payment of approximately $770,000 to Antisense and returned to Antisense, for no consideration, the shares of Antisense owned by us. We also agreed to transfer to Antisense all data, reports, records and materials resulting from our development activities and all ATL1103 drug compound in our possession. The settlement agreement provides for the release by each party of all obligations and liabilities under the Antisense License Agreement. In connection with the settlement and return of shares, we recorded $1.0 million of expense within other (expense)/income.

(c) Commitments to Taro Pharmaceuticals Industries Ltd.

In December 2016, we acquired the U.S. marketing rights to Keveyis® (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. (“Taro”). Keveyis is approved in the U.S. to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Keveyis has received orphan drug exclusivity status in the U.S through August 7, 2022. Under the terms of an asset purchase agreement, we will pay $7.5 million prior to the Company’s planned April 2017 launch of Keveyis in the United States, as well as an aggregate of $7.5 million in potential milestones upon the achievement of certain product sales targets. Taro has agreed to continue to manufacture Keveyis for us under an exclusive supply agreement through the orphan exclusivity period. We are obligated to purchase certain annual minimum amounts of product totaling approximately $29 million over a six-year period. The supply agreement may extend beyond the orphan exclusivity period unless terminated by either party pursuant to the terms of the agreement. If terminated by Taro at the conclusion of the orphan exclusivity period, we have the right to manufacture the product on our own or have the product manufactured by a third party on our behalf.

12. LONG TERM DEBT

Long term debt as at year ended December 31, 2016 and December 31, 2015 consist of the following (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Long term debt	20,000	-
Debt issuance costs	(276)	-
Debt discount	(1,290)	-
Total long term debt	18,434	-

On December 28, 2016, the Company entered into a loan and security agreement (the “Loan Agreement”) with Oxford Finance LLC (“Oxford”) and Horizon Technology Finance Corporation (“Horizon”). The Loan Agreement provided for a $40 million credit facility, of which $20 million was borrowed initially. Under the Loan Agreement, the Company has access to two additional tranches of $10 million each, which would be available to the Company subject to the achievement of certain specified milestones.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. LONG TERM DEBT (CONTINUED)

The borrowings pursuant to the Loan Agreement mature after 48 months. The Loan Agreement provides for interest-only payments initially for the first 18 months of the loan followed by an amortization period of 30 months, provides for a final payment fee equal to 8% of the amount borrowed, and interest payable at an annual rate equal to the sum of 8.22% plus the greater of 0.53% or the 30-day US LIBOR rate. The credit facility provides that if the Company satisfies certain milestones and borrows the final $10 million tranche, the interest-only period would be extended by an additional six months and the amortization period would be 24 months. The Company has granted a security interest in substantially all of its existing assets and assets acquired by the Company in the future, including intellectual property. The Loan Agreement contains facility and prepayment fees, and customary affirmative and negative covenants, including a financial covenant regarding minimum amounts of net revenue and events of default and restricts the payment of cash dividends. The Loan Agreement contains a material adverse change clause whereby a material adverse change in the Company's business, operations or financial condition would be considered an event of default whereby the lenders could declare all amounts under the Loan Agreement as immediately due and payable. We incurred $1.3 million in debt discounts and $0.3 million of debt issuance costs relating to this Loan Agreement which have been recorded as a reduction to the long-term debt. These amounts will be amortized over the outstanding period of the debt to interest expense using the effective interest rate method.

In connection with the execution of the Loan Agreement, we issued warrants to the Lenders to purchase an aggregate of 428,571 ordinary shares at an exercise price equal to $2.45 per share. The warrants expire after ten years.

Future principal payments due under the Loan Agreement are as follows (in thousands):

	Principal Payments
	$'000
2017	-
2018	4,667
2019	8,000
2020	7,333
Total future payments	20,000

13. WARRANTS

Common stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, Derivatives and Hedging — Contracts in Entity's Own Equity (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. The balance as at December 31, 2016 in connection with private equity placement is a liability of $11,090 thousand (2015: nil). The fair value of warrants in connection with loan agreement included in equity as at December 31, 2016 is $525,000 (2015: nil).

Warrants outstanding and warrant activity for the year ended December 31, 2016 is as follows:

	Classification	**Exercise Price**	**Expiration Date**	**Warrants Issued**	**Warrants Exercised**	**December 31, 2016**
Warrants in connection with private equity placement	Liability	$2.50	June 28, 2022	7,000,000	-	7,000,000
Warrants in connection with loan agreement	Equity	$2.45	December 28, 2026	428,571	-	428,571
				7,428,751		7,428,751

Warrants outstanding and warrant activity for the year ended December 31, 2015 are nil.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

14. LONG TERM ACCRUED LIABILITIES

Long term accrued liabilities as at year ended December 31, 2016 and December 31, 2015 are as follows (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Supply agreement liability in relation to Keyevis	25,078	-

Refer to note 8 of Notes to Consolidated Financial Statements for further information regarding supply agreement liability in relation to Keyevis.

15. FAIR VALUE MEASUREMENTS

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We are required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described as follows:

Level 1: Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.

Level 2: Valuations based on quoted prices for similar assets or liabilities, or quoted prices in markets that are not active, and for which all significant inputs are observable, either directly or indirectly.

Level 3: Valuations that require inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The following tables summarise the valuation of the Company's financial instruments carried at fair value by the above pricing categories as of December 31, 2016 and December 31, 2015 (in thousands):

	As of December 31, 2016			
	Level I	Level II	Level III	Total
	$'000	$'000	$'000	$'000
Liabilities				
Warrant Liabilities	-	-	11,090	11,090
Total liabilities	-	-	11,090	11,090

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

15. FAIR VALUE MEASUREMENTS (CONTINUED)

	As of December 31, 2015			
	Level I	**Level II**	**Level III**	**Total**
	$'000	**$'000**	**$'000**	**$'000**
Financial assets:				
Cash and cash equivalents	45,296	-	-	45,296
Non-current assets	-	550	-	550
Total financial assets	45,296	550	-	45,846

Our foreign currency forward contracts are classified within Level II because of the use of observable inputs for similar derivative instruments in active markets, or quoted prices for identical or similar instruments in markets that are not active, and are directly or indirectly observable, and are classified as prepaid expenses and other current assets. The noncurrent asset comprising of our investment in ATL common stock, up until the time our investment was returned to ATL was classified as Level II as we discounted the active market quoted price of the security to reflect our contractual restriction on selling the investment. Level 3 instruments consist of the common stock warrant liability.

The fair values of the outstanding warrants were measured using the Black-Scholes option-pricing model. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

Because of their short term nature, the amounts reported in the balance sheet for cash and cash equivalents, and accounts payable approximate fair value.

16. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

The Company enters into certain derivative financial instruments, when available on a cost-effective basis, to mitigate its risk associated with changes foreign currency exchange rates.

To reduce our currency exposure, we used a hedging program from the fourth quarter of 2013 through the second quarter of 2015. The foreign currency forward contracts used in our hedging program were not entered into for speculative purposes and, although we believe they served as effective economic hedges, we did not seek to qualify for hedging accounting. In 2014, our operations continued to shift to the United States, but a large portion of our cash and cash equivalents were still held in foreign currencies. In the first half of 2015, all of our forward contracts expired.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY

The issued share capital for the Company during the year ended December 31, 2016 and December 31, 2015 can be summarised as follows:

	Ordinary shares with par value of €1.00 each	Ordinary shares with par value of €1.00 each	Issued Share Capital at par
	No of shares	No of shares	$'000
Opening Balance as at 1 January 2016	40,000	21,205,382	256
On December 22, 2016 14,000,000 ordinary shares issued, par value $0.01	-	14,000,000	140
Exercise of stock options	-	129,644	1
Closing Balance as at 31 December 2016	40,000	35,335,026	397
Opening Balance as at 1 January 2015	-	9,700,789	97
In February 2015, private placement of 4,761,078 shares issued, par value $0.01	-	4,761,078	48
On May 26, 2015, 40,000 deferred ordinary shares issued, par value €1.00	40,000	-	44
In June 2015, private placement of 2,284,414 shares issued, par value $0.01	-	2,284,414	23
On June 30, 2015 private placement of 2,062,677 shares issued, par value $0.01	-	2,062,677	21
US Non Accredited Shares Repurchases	-	(24,955)	-
Reallocation of ordinary shares not tendered	-	(78,621)	(1)
On October 22, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering	-	2,500,000	25
Closing Balance as at 31 December 2015	40,000	21,205,382	256

On December 22, 2016, we entered into a Share Purchase Agreement to sell $35 million of our shares in a private placement, 14,000,000 ordinary shares were issued at a subscription price of $2.50 per share, par value $0.01.

Stock options of 129,644 ordinary shares were exercised during the year at a price of $2.30 per share, par value $0.01. Consideration received was $120,000. All amounts in respect to the allotted share capital have been called up and fully paid at the balance sheet date.

Voting Rights and Privileges

As of December 31, 2016 and December 31, 2015, the authorized share capital of the Company is €40,000 and $7,000,000 divided into 40,000 deferred ordinary shares of €1.00 each, 600,000,000 ordinary shares of $0.01 each, par value and 100,000,000 preferred shares of $0.01 each, par value.

As of December 31, 2016, there were 40,000 authorized deferred ordinary shares of €1.00 each (2015: 40,000) and 35,335,026 ordinary shares of $0.01 each outstanding (2015: 21,205,382), respectively.

The holders of ordinary shares are entitled to one vote for each ordinary share held at all general meetings of shareholders without limitation. The holders are entitled to receive dividends if and when declared by the Board of Directors or by the Company in general meeting, provided no dividend shall exceed the amount recommended by the Board of Directors.

No dividends have been declared or paid since inception. The holders are entitled to share rateably in the assets available for distribution to shareholders, in the event of any voluntary or involuntary liquidation.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY (CONTINUED)

Voting Rights and Privileges (continued)

The deferred ordinary shares are issued in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The deferred ordinary shares carry no voting rights and are not entitled to any dividend or distribution.

Equity Financings

On December 22, 2016, we raised $32.7 million, net of transaction costs, in a private placement of ordinary shares and warrants. We issued and sold 14,000,000 ordinary shares of common stock at a purchase price of $2.50 per ordinary share as well as warrants to purchase 7,000,000 shares. The warrants are exercisable at a price of $2.50 per share beginning on June 28, 2017 and expire in five years from the date June 28, 2017. The terms of the warrants state, in the event of a sale of the Company, the terms of the warrants issued to the 2016 Investors in the 2016 Private Placement require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrant agreements). Therefore we are required to account for these warrants as liabilities and record at fair value at each reporting period. Fair value for these warrants was initially determined upon issuance using the Black-Scholes Model and were revalued at fair value as of December 31, 2016. The resulting decrease in fair value resulted in an unrealized gain of $0.6 million. As of December 31, 2016, the fair value of these warrants of $10.0 million was recorded as a long-term liability on our consolidated balance sheet.

Shares Reserved for Issuance

There were 2,591,250 and 1,951,022 shares of ordinary shares in the Company reserved for future issuance upon exercise of stock options as of December 31, 2015 and 2016, respectively.

Stock-based Compensation

The Board of Directors approve the granting of awards to our officers, directors, employees and third party-consultants. Under these grants, the beneficiaries are given the right to acquire new shares of common stock at a pre-determined option price. The purpose of the grants is to assist us in attracting, retaining and motivating officers, employees, directors and consultants. In addition, these awards provide us with the ability to provide incentives that are directly linked to the performance of our business and the related increase in shareholder value.

Our awards have terms that range from five to ten years. As determined by our Board of Directors, our awards vest over service periods ranging up to four years or upon achievement of defined performance or market criteria such as the vesting of certain awards upon our IPO or awards that are accelerated when the fair value of our stock price reaches defined targets.

The exercise price for each stock option is determined by the Board of Directors based upon considerations such as the fair value of the underlying ordinary shares and certain market conditions. For options granted prior to our October 22, 2015, IPO, the determination of the fair value of our common stock takes into account the price at which our shares were being quoted on the NOTC, recent equity financings and our valuations calculated with the assistance of third-parties.

On July 21, 2015, we cancelled 465,262 of our options for certain employees that were not vested and for which service was expected to be rendered and concurrently replaced these with 586,710 options. We accounted for the cancellation and replacement as a modification whereby we determined value of the original options based on current assumptions, without regard to the assumptions made on the grant date. We then compared the fair value of the modified award to the fair value of the original options immediately before the terms were modified, measured based on the share price and other pertinent factors on the date of the modification The incremental value of $468,000 was recorded over the remaining requisite service periods as these awards are expected to vest.

On September 8, 2015, we effected a 1-for-11 reverse stock split of our ordinary shares. In conjunction with the reverse stock split, we adjusted our outstanding stock options by the same ratio.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY (CONTINUED)

Stock-based Compensation (continued)

On October 22, 2015, we converted all of our Cortendo AB awards which were previously denominated in Swedish Krona (SEK) and Norwegian Kroner (NOK), into awards to acquire shares in Strongbridge Biopharma plc which were denominated in U.S. dollars. For the stock options denominated in NOK, the calculation was based on 8.1935 NOK per U.S. dollars. Due to the effects of foreign exchange related to the exercise price, we accounted for the conversion as a modification whereby we determined value of the original options based on current assumptions, without regard to the assumptions made on the grant date. We then compared the fair value of the modified award to the fair value of the original options immediately before the terms were modified, measured based on the share price and other pertinent factors on the date of the modification. Because the effected options were vested, the incremental value of $325,000 was recorded as expense during the period ended December 31, 2015.

For the awards denominated in SEK which were classified as liability awards, we accounted for the conversion as a modification whereby we determined the value of the original options based on current assumptions, without regard to the assumptions made on the grant date. We then compared the fair value of the modified award to the fair value of the original options immediately before the terms were modified, measured based on the share price and other pertinent factors on the date of the modification. The incremental value was recorded as expense in the statement of operations. The liability awards were fully vested as of October 22, 2015 and therefore the resulting liability after modification of $1.5 million, was reclassified from liability to additional paid-in capital on October 22, 2015. As these stock options are now equity-classified and fully vested, we will not remeasure these stock options in the future.

A summary of the outstanding stock options as of December 31, 2016 and 2015 is as follows:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
				$'000
Outstanding-January 1, 2015	925,077	$8.01	3.72	1,011
Granted	1,710,530	$16.87		
Forfeited and cancelled	(44,087)	$7.60		
Exercised	-			
Outstanding-December 31, 2015	2,591,520	$13.59	5.97	1,844
Vested and exercisable-December 31, 2015	727,280	$6.53	3.12	1,844
Vested and expected to vest-December 31, 2015	2,591,520	$13.59	5.97	1,844
Outstanding January 1, 2016	2,591,520	$13.59	5.97	1,844
Granted	1,169,600	$4.28		
Forfeited and cancelled	(329,518)	$12.85		
Exercised	181,818	$1.32		
Outstanding-December 31, 2016	3,249,784	$11.00	6.89	-
Vested and exercisable-December 31, 2016	1,158,660	$11.37	4.91	-
Vested and expected to vest-December 31, 2016	2,860,743	$10.73	6.52	-

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY (CONTINUED)

Stock-based Compensation (continued)

Included in the stock options outstanding at December 31, 2016, are unvested stock options to purchase 143,302 shares at a weighted average exercise $18.80 per share for which the vesting of certain tranches will accelerate if the fair value per share of our stock reaches $16.11, $31.46 or $37.62 for the respective grantee. In addition, the options outstanding include 106,738 shares that vest upon a market appreciation event so long as it occurs prior to May 26, 2019 of which all were unvested as of December 31, 2016 and 106,738 shares that will vest upon the one year anniversary of the market appreciation event of which all were unvested as of December 31, 2016. The market appreciation event is defined as the last trading day in the period in which the closing stock price on each of 20 consecutive trading days reported on NASDAQ has been at least $30.14 or $33.66 for the respective grantee.

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of our common stock as of December 31, 2016, since the estimated fair value is less than the exercise price for all stock options, there is not any intrinsic value.

Stock-based compensation expense

We recognized stock-based compensation expense for employees and non-employees in the accompanying consolidated statements of comprehensive income as follows (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Research and development	601	793
General and administrative	4,005	3,147
Total stock-based compensation	4,606	3,940

Included in these amounts was stock compensation expense (credit) attributed to liability-classified awards of, $0 and $359,000, for the years ended December 31, 2016 and 2015, respectively. The total income tax benefit recognized in the income statement for share-based compensation arrangements was $1.9 million, and $0 for 2016 and 2015, respectively.

As of December 31, 2016, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $6.8 million, which we expect to recognize over an estimated weighted-average period of 2.46 years.

In determining the estimated fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

The fair value of stock option awards was estimated with the following assumptions:

	Year Ended December 31, 2016	Year Ended December 31, 2015
Expected term (in years)	5.90	3.23
Risk-free interest rate	1.21% - 2.23%	0.0% - 0.6%
Expected volatility	78.1% - 83.6%	79.0% - 83.1%
Dividend rate	-%	-%

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY (CONTINUED)

Restricted Stock Units Grants

On February 26, 2016, our board of directors approved grants of restricted stock units, or RSUs, to Messrs. Pauls and Davis, and Dr. Cohen in the amounts of 40,000, 20,000 and 13,000, respectively. On June 13, 2016 and November 23, 2016, our board of directors approved grants of RSUs for Dr. Cohen in the amounts of 5,000 and 4,000, respectively. These RSUs vest, with respect to 100% of the grants, on the second anniversary following the date of grant, provided that the executive is employed by the Company on such vesting date. All RSUs will fully vest upon a change of control of our company. If and when the RSUs vest, the Company will issue to the executive one ordinary share of the Company for each whole RSU that has vested, subject to satisfaction of the executive's tax withholding obligations. The RSUs will cease to be outstanding upon such issuance of shares.

Capital & Reserves

	Issued Share Capital at par	Share Premium	Other Reserves	Warrant Reserves	Non-controlling Interest	Retained Earnings
	$'000	$'000	$'000	$'000	$'000	$'000
Opening Balance as at January 1, 2016	256	165,719	5,191	-	564	(80,803)
On December 22, 2016 14,000,000 ordinary shares issued, par value $0.01 net of fair value of warrants granted	140	23,132	-	-	-	-
Costs on issuance of shares	-	-	(2,345)	-	-	-
Exercise of stock options 129,644 ordinary shares issued, par value $0.01	1	119	-	-	-	-
Acquisition of non-controlling interest	-	-	(972)	-	(442)	-
Stock based compensation	-	-	4,606	-	-	-
Issuance of warrants related to loan agreements	-	-	-	525	-	-
Net loss for the year	-	-	-	-	(122)	(48,597)
Closing Balance as at December 31, 2016	397	188,970	6,480	525	-	(129,400)

On December 22, 2016, we raised $35 million in aggregate proceeds in a private placement. According to the terms of the Securities Purchase Agreement, dated December 22, 2016, we issued and sold 14,000,000 ordinary shares at a purchase price of $2.50 per ordinary share, as well as warrants to purchase 7,000,000 ordinary shares to the investors. Issuance costs amounted to $2.34 million.

Stock options of 129,644 ordinary shares were exercised during the year at a price of $2.30 per share, par value $0.01. Consideration received was $120,000.

The non-controlling interest results from the 0.418% of Cortendo AB shares not acquired by Strongbridge Biopharma plc pursuant to the exchange offer that expired September 3, 2015. In September 2016, the non-controlling interest was acquired by the Company.

On December 28, 2016, we entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Horizon Technology Finance Corporation ("Horizon") (collectively, the "Lenders"). The Loan Agreement provided for a $40 million credit facility, of which $20 million was borrowed initially. Under the Loan Agreement, we have access to two additional tranches of $10 million each which are be available to us subject to the achievement of certain specified milestones. Upon the execution of the Loan Agreement, we issued warrants to the Lenders to purchase an aggregate of 428,571 ordinary shares at an exercise price equal to $2.45 per share (the "Lender Warrants"). The Lender Warrants are immediately exercisable and expire after ten years. The Lender Warrants issued to the Lenders include a provision requiring us to file a registration statement to provide for the public resale of the ordinary shares to be issued upon exercise of the Lender Warrants.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY (CONTINUED)

Capital & Reserves

	Issued Share Capital at par	Share Premium	Other Reserves	Non-controlling Interest	Retained Earnings
	$'000	$'000	$'000	$'000	$'000
Opening Balance as at January 1, 2015	97	55,467	480	(54)	(37,223)
On February 10, 2015, private placement of 4,761,078 shares issued, par value $0.01	48	25,726	-	-	-
On May 26, 2015, 40,000 deferred ordinary shares issued, par value €1.00/$1.098	44	0	-	-	-
In June 2015, private placement of 2,284,414 shares issued, par value $0.01	23	32,540	-	-	-
On June 30, 2015 private placement of 2,062,677 shares issued, par value $0.01	21	33,152	-	-	-
US Non Accredited Shares Repurchases	-	-	(412)	-	-
Reallocation of ordinary shares not tendered	(2)	(616)	-	618	-
On October 22, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering	25	19,450	-	-	-
Stock based compensation	-	-	5,123	-	-
Net loss for the year	-	-	-	-	(43,580)
Opening Balance as at December 31, 2015	256	165,719	5,191	564	(80,803)

On February 10, 2015, following shareholder approval the Company entered into a share purchase agreement with investors and issued 4,761,078 ordinary shares for $26.4 million. Issuance costs amounted to $605,000.

On June 29 and 30, 2015, the Company raised $33.2 million in aggregate gross proceeds in a private placement of common shares. Issuance costs amount to $662,000. The subscription price was $16.10 per share and the Company issued 2,284,414 new shares to the investors.

On June 30, 2015, the Company acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. Under the terms of the acquisition agreement, the Company issued to Aspireo Pharmaceuticals 2,062,677 ordinary shares, which had a value of $33.2 million. In connection with this acquisition, we made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of $3.0 million, which represents the repayment of amounts previously granted by OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17. SHAREHOLDERS' EQUITY (CONTINUED)

Capital & Reserves (continued)

In order to effect a corporate reorganization, on September 8, 2015 the Company settled an exchange offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis. Non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc.

On May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc), was incorporated under the laws of Ireland and issued 40,000 ordinary shares issued, par value €1.00/$1.098. The ordinary shares of €1.00 each were redesignated into deferred ordinary shares of €1.00 each, par value, on August 7, 2015 and carry no voting rights and are not entitled to any dividend or distribution.

On October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the Company initiated an initial U.S. public offering (IPO) of 2,500,000 ordinary shares at a price of $10.00 per share. The aggregate net proceeds received from the IPO were $19.5 million. The shares began trading on The NASDAQ Global Select Market under the symbol "SBBP". On October 20, 2015, trading ceased on the Norwegian Over-The-Counter Market, or NOTC.

18. TAXES

The reconciliation from tax loss to tax benefit for the year end December 31, 2016 and 2015 can be summarized as follows:

	Year Ended December 31, 2016 $'000	Year Ended December 31, 2015 $'000
Loss before taxes	51,357	44,083
Effective rate of tax of 5.14%/1.0%	2,638	450
Tax benefit	2,638	450

For the years ended December 31, 2016 and 2015, the components of loss before taxes were as follows (in thousands):

	Year Ended December 31, 2016 $'000	Year Ended December 31, 2015 $'000
Sweden	(16,433)	(33,960)
Ireland	(11,653)	(191)
Cayman Islands	(19,550)	(8,722)
U.S.	(3,721)	(1,210)
Total	(51,357)	(44,083)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

18. TAXES (CONTINUED)

The components of tax for the years ended December 31, 2016 and 2015 were as follows (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
Current tax expense (benefit):	**$'000**	**$'000**
Sweden	-	-
Ireland	22	-
U.S. Federal	151	-
U.S. State	73	-
Total	246	-
Deferred tax expense (benefit):		
Sweden	-	212
Ireland	-	(24)
U.S. Federal	(5,793)	(17,543)
U.S. State	(678)	(1,233)
Change in valuation allowance	3,587	18,138
Total	(2,638)	(450)

With the exception of the newly formed U.S. Entity, we have incurred net operating losses since inception. For the Ireland and Swedish operations, we have not reflected any benefit of net operating loss carryforwards (NOLs) in the accompanying financial statements. For the newly formed U.S. entity, as a result of the intercompany service agreements, it is more likely than not this entity will be in taxable income and recognize all deferred tax assets. Due to the recording of a full impairment of the BioPancreate intellectual property in the current year at BioPancreate, we have established a full valuation allowance against all prior deferred tax assets.

Deferred taxes are recognized for temporary differences between the bases of assets and liabilities for financial statement and tax purposes. The tax effect of temporary differences that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	Year Ended December 31, 2016	Year Ended December 31, 2015
Deferred tax assets:	**$'000**	**$'000**
Net operating loss carryforwards	24,433	22,039
Stock based compensation	1,870	-
Other deferred activity	96	-
Tax credits	9,135	9,135
Capitalized research and development costs	161	161
Total deferred tax assets	35,695	31,335
Valuation allowance	(33,738)	(30,150)
Deferred tax assets recognized	1,957	1,185
Deferred tax liabilities:		
Warrants	(358)	-
Acquired intangible assets	-	(2,111)
Total deferred tax liabilities	(358)	(2,111)
Net deferred tax liabilities	1,599	(926)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

18. TAXES (CONTINUED)

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses in Ireland and Sweden, we have concluded that it is more likely than not that the benefit of our deferred tax assets will not be realized. Currently, as a result of intercompany service agreements that provide a source of taxable income going forward, the U.S. entity is more likely than not to realize its deferred tax assets. Separately, as a result of recording a full impairment of the BioPancreate intellectual property, we have recorded a full valuation allowance against the prior federal attributes and all existing state attributes related to BioPancreate. The valuation allowance increased by approximately $18.1 million and $3.3 million during the year ended December 31, 2016 and 2015, respectively, due primarily to net operating losses.

The Company's effective income tax rate differs from the ultimate parent company, Strongbridge Biopharma plc's, Irish domestic statutory rate of 12.5% for the year ended December 31, 2016 and December 31, 2015. In December 31, 2014, the effective income tax rate differs from previous ultimate parent company, Cortendo AB's, Swedish domestic tax rate of 22% as follows:

	Year Ended December 31, 2016	Year Ended December 31, 2015
Ireland statutory income tax rate	12.50%	12.50%
Swedish statutory income tax rate	-	-
Foreign tax differential between Sweden, U.S., Cayman Island and Ireland	2.28%	15.70%
Federal tax credits	-	12.10%
Change in valuation allowance	(6.69%)	(41.20%)
State income taxes	0.92%	-
Permanent differences	1.59%	-
FX measurement of Swedish DTS	(5.42%)	(5.41%)
Other	(0.04%)	7.31%
Effective income tax rate	5.14%	1.00%

At December 31, 2016, we had approximately $70.4 million of Swedish NOLs and approximately $12.5 million of Ireland NOLs, which have an indefinite life, and approximately $37.1 million of U.S. federal and $37.2 million of state NOLs, which begin to expire in 2031. Through December 31, 2015 we operated through a permanent establishment in both Sweden and the United States. Relief is granted by way of crediting the U.S. tax against the Swedish tax. This tax credit can never exceed the Swedish tax on the income. Since the tax rate is higher in the United States than in Sweden, the Swedish taxable carryforward losses of $70.4 million can only generate a tax benefit if income is derived from sources other than the permanent establishment in the United States. Beginning January 1, 2016, the US operations that were not part of BioPancreate Inc occurred in a newly formed US corporation. There were no operating losses generated during 2016 in the U.S. except for a minor state NOL at BioPancreate.

At December 31, 2016, we had $8.9 million of U.S. federal orphan drug tax credit carryforwards, which begin to expire in 2032, and $167,000 of U.S. federal research and development tax credit carryforwards, which begin to expire in 2031. The orphan drug credit carryforward is attributable to the permanent establishment of the Swedish entity within the U.S.

Utilization of the NOLs may be subject to limitations under Swedish tax regulations or U.S. Internal Revenue Code Section 382 if there is a greater than 50% ownership change as determined under applicable regulations.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

19. SEGMENT INFORMATION

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. Our material long-lived assets, which primarily consists of in-process research and development, reside in the United States, Sweden and Cayman Islands.

20. SUBSIDIARY INFORMATION

The Company has four wholly owned subsidiaries, Strongbridge U.S Inc., a Delaware corporation, Cortendo AB, a company organized under the laws of Sweden, BioPancreate Inc., a Pennsylvania corporation, and Cortendo Cayman Ltd., an exempted company incorporated in the Cayman Islands. The Company holds 100% of the ordinary shares of the direct subsidiary Cortenda AB. Cortendo AB holds 100% of the ordinary shares of Strongbridge U.S. Inc. and 100% of the ordinary shares of Cortendo Cayman Ltd. Strongbridge U.S. Inc. holds 100% of the ordinary shares in BioPanceate Inc.

In order to effect a corporate reorganization, on September 8, 2015 we settled an exchange offer, which we refer to as the Exchange Offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis and non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc. In September 2016, we acquired the non-controlling interest in Cortendo AB, after which Cortendo AB became a wholly owned subsidiary of Strongbridge Biopharma plc.

Following the settlement of the Exchange Offer, Strongbridge Biopharma plc became the parent of Cortendo AB and its subsidiaries. As a result of the settlement of the Exchange Offer, the historical financial statements of Cortendo AB became, for financial reporting purposes, the historical consolidated financial statements of Strongbridge Biopharma plc and its subsidiaries as a continuation of the predecessor. During the period from the settlement date of the Exchange Offer through the acquisition of all the shares of Cortendo AB not tendered in the Exchange Offer, the 0.418% interest in Cortendo AB was accounted for as a non-controlling interest.

As of March 1, 2017, the Company had the following subsidiaries:

Name	Nature of Business	Group Share %	Registered Office and Country of Incorporation
BioPancreate Inc.	Operating	100%	900 Northbrook Drive Suite 200 Trevose Pennsylvania 19053
Cortendo AB (publ)	Operating	100%	Box 47 433 21 Partille Gothenburg Sweden
Cortendo Cayman Ltd	Operating	100%	Maples Corporate Services PO Box 309 Ugland House Grand Cayman KY1-1104
Strongbridge U.S. Inc.	Operating	100%	Corporate Trust Center Lmt 1209 Orange Street Wilmington, Delaware 19801

21. EMPLOYEES

During the year ended December 31, 2016, the Company had an average of 25 full-time employees, each of whom is working in the United States. Of these full-time employees, 9 were engaged in research and development and 15 were engaged in general and administrative activities.

During the year ended December 31, 2015, the Company had an average of 15 full-time employees including 24 working in the United States and one employee working in Sweden. Of these full-time employees, 11 were engaged in research and development and 14 were engaged in general and administrative activities.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

21. EMPLOYEES (CONTINUED)

The employee costs for the year ended December 2016 and 2015 can be summarised as follows:

	Year Ended December 31, 2016	Year Ended December 31, 2015
	$'000	$'000
Wages, salaries, bonuses and fringe benefits	7,278	4,758
Pension benefits	-	-
Payroll taxes	314	291
Stock-based compensation expense	4,606	3,940
	12,198	8,989

22. DIRECTORS' REMUNERATION

Name	Year	Fees Earned or Paid in Cash $	Salaries and Bonuses $	Share Based Payment $
John Johnson	2016	95,982	-	171,999
	2015	65,050	-	-
Richard Kollender	2016	55,247	-	145,443
	2015	33,126	-	-
Garheng Kong	2016	45,185	-	161,175
	2015	12,934	-	-
Jeffrey Sherman[2]	2016	10,371	-	18,204
	2015	-	-	-
Mårten Steen	2016	47,500	-	163,081
	2015	35,833	-	-
Hilde Steineger	2016	47,500	-	163,081
	2015	35,833	-	-
H. Joseph Reiser[1]	2016	-	-	-
	2015	18,749	-	-
Espen Tidemann Jørgensen[1]	2016	-	-	-
	2015	14,348	-	-
Ernest Eichenberg III[1]	2016	-	-	-
	2015	10,938	-	-
Joseph M. Mahady[1]	2016	-	-	-
	2015	22,029	-	-
Eigil Stray Spetalen[1]	2016	-	-	-
	2015	21,349	-	-
Matthew Pauls	2016	-	666,900	1,871,959
	2015	-	669,903	-

(1) Messrs. Reiser, Eichenberg, Jørgensen, Spetalen and Mahady resigned from the board of directors of Cortendo AB in 2015.

(2) Dr. Sherman joined the board of directors in October 2016.

No pension payments or other benefits were payable and no gains arose on the exercise of share options by the directors during the current or preceding financial year.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

23. AUDITOR'S REMUNERATION

Fee Category	Year Ended December 31, 2016 $'000	Year Ended December 31, 2015 $'000
Audit Fees	619	1,309
Audit-Related Fees	-	70
Tax Advisory Fees[1]	118	71
Other non-audit Fees[2]	-	365
Reimbursement of auditor's expenses	-	5
Total Fees	737	1,820

(1) Audit fees consist of fees for the audit of our financial statements, the review of our interim financial statements and statutory audits. For 2015, it also included the audit of Aspireo in 2015 and services associated with our registration statement on Form F-1.

(2) Audit-related fees incurred consist of other services not audited related.

(3) Tax fees consists of fees incurred for tax compliance, tax advice and tax planning and includes fees for tax return preparation and tax consulting.

(4) Other fees consist of fees incurred for the Irish redomicile and other services.

The aggregate fees included in the Audit Fees are billed for the fiscal year. The aggregate fees included in the Audit-related fees and Tax Fees are fees billed in the fiscal year.

All such accountant services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below.

The fees paid to Ernst & Young Ireland in respect of the audit of the group accounts were $126,000 in 2016 (2015: $180,000). In addition, Ernst & Young Ireland received fees of $10,881 for tax compliance services (2015: nil). Ernst & Young Ireland did not receive any fees for other assurance services or fees for non-audit services in 2016 or 2015.

24. RELATED PARTY TRANSACTIONS

Refer to Directors' report on page 49 for further information.

25. SUBSEQUENT EVENTS

On March 31, 2017 we entered into an amendment to the Loan Agreement that was made effective as of January 27, 2017 and provided for an extension to the dates by which the Company's Swedish subsidiary was required to enter into security documents granting security interests on certain of its assets in favor of Oxford, as collateral agent for the Lender, and to increase the amount of debt the Company can incur under, and the amount of cash collateral it can provide for purposes of, its corporate credit card program from $100,000 to $250,000. In connection with the amendment, the Company paid $150,000 to the Lenders.

There were no other significant subsequent events from the end of the year until the date of signing of this report that would require an adjustment to or disclosure in the financial statements.

26. APPROVAL OF FINANCIAL STATEMENTS

The financial statements were approved and authorised for issue by the Board of Directors and signed on 11 April 2017.

COMPANY BALANCE SHEET

	Notes	2016 $ '000	2015 $ '000
ASSETS			
Fixed assets			
Intangible assets	3	40,177	-
Financial assets	4	58,102	142,418
Current assets			
Debtors – amounts falling due within one year	6	7,119	260
Cash at bank and in hand	5	42,339	21,782
Total assets		147,737	164,460
LIABILITIES AND SHAREHOLDERS' EQUITY			
Capital and reserves			
Called up share capital - equity	9	397	256
Share premium account	10	349,282	326,031
Other reserves	10	5,632	2,489
Retained earnings		(270,506)	(167,615)
Total Shareholders' equity		84,805	161,161
Creditors			
Creditors – amounts due within one year	7	26,764	3,299
Creditors – amounts falling due after more than one year	8	36,168	-
Total liabilities		62,932	3,299
Capital and reserves and liabilities		147,737	164,460

The Company Balance Sheet was approved and signed on behalf by the Board of Directors on 11 April 2017:

/s/ Matthew Pauls
Matthew Pauls
Director

/s/ Richard Kollender
Richard Kollender
Director

COMPANY STATEMENT OF CHANGES IN EQUITY
(In thousands except share amounts)

	Called up Share Capital Equity	Share Premium Account	Other Reserves	Retained Earnings	Total Equity
	$'000	$'000	$'000	$'000	$'000
Balance at January 1, 2016	256	326,031	2,489	(167,615)	161,161
Net loss for the year	-	-	-	(102,891)	(102,891)
Stock-based payment expense for the year	-	-	4,606	-	4,606
Issuance of shares, net of fair value of warrants granted	140	23,132	-	-	23,272
Costs on issuance of shares	-	-	(2,345)	-	(2,345)
Exercise of stock options	1	119	-	-	120
Issuance of warrants related to loan agreement	-	-	882	-	882
Balance at December 31, 2016	397	349,282	5,632	(270,506)	84,805

	Called up Share Capital Equity	Share Premium Account	Other Reserves	Retained Earnings	Total Equity
	$'000	$'000	$'000	$'000	$'000
Balance at incorporation (May 26, 2015)	-	-	-	-	-
Net loss for the period	-	-	-	(167,615)	(167,615)
Share-based payment expense for the period	-	-	618	-	618
Issuance of deferred ordinary shares	44	-	-	-	44
Issuance of shares on exchange	2,058	306,581	-	-	308,639
Reverse stock split of 1-11 ordinary shares	(1,871)	-	1,871	-	-
Issuance of shares in initial public offering, net	25	19,450	-	-	19,475
Balance at December 31, 2015	256	326,031	2,489	(167,615)	161,161

The accompanying notes are an integral part of the Company Financial Statements.

NOTES TO COMPANY BALANCE SHEET

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. Basis of preparation

The financial statements of Strongbridge Biopharma plc ("Strongbridge" or the "Company"), have been prepared under the historical cost convention in accordance with FRS 102 - The Financial Reporting Standard applicable in the UK and Ireland (”FRS 102”), comprising applicable company law and the accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland (Generally Accepted Accounting Practice in Ireland). The accompanying Balance Sheet of the Company is presented on a stand-alone basis, including related party transactions.

The financial statements of the Company have been prepared on the going concern basis. The directors have taken into account all relevant information covering a period of at least twelve months from the date of approval of the financial statements. The directors believe that the Company is well placed to manage its business risks successfully despite the current uncertain economic outlook. After making enquiries, the directors have a reasonable expectation that the Company has access to adequate resources to continue in operational existence for the foreseeable future. On that basis, the directors consider it appropriate to continue the use of the going concern assumption.

Strongbridge Biopharma plc is availing of the reduced disclosure framework under FRS 102 on the basis that Strongbridge Biopharma plc itself meets the definition of a qualifying entity, being a member of a group that prepare publicly available financial statements which give a true and fair view, and in which Strongbridge Biopharma plc is consolidated. The consolidated financial statements, in which these Company financial statements are included are available to the public at its registered office.

Strongbridge Biopharma plc has taken advantage of the following disclosure exemptions under FRS 102:

a. the requirements of section 4 Statement of Financial Position- Paragraph 4.12 (a) (iv).
b. the requirements of section 7 Statement of Cash Flows and Section 3 Financial Statement Presentation paragraph 3.17(d).
c. the requirements of Section 26 Share based Payment: paragraph 26.18 (b), 26.19 to 26.21 and 26.23.
d. requirements of Section 33 Related Party Disclosures, paragraph 33.7.

The accounting policies which follow set out those policies which apply in preparing the financial statements for the year ended December 31, 2016.

b. Judgements and key sources of estimation uncertainty

The preparation of financial statements requires management to make judgements, estimates and assumptions that affect the amounts reported for assets and liabilities as at the statement of financial position date and the amounts reported for revenues and expenses during the year. However, the nature of estimation means that actual outcomes could differ from those estimates. The following judgements have the most significant effect on amounts recognised in the financial statements.

Fair value of supply agreement liability in relation to Keveyis

We have concluded that the supply price payable by the Company in relation the acquisition of Keveyis exceeds fair value and management estimation was required to determine the fair value of liabilities arising. Management utilized a discounted cash flow model incorporating a probability assumption to estimate fair value, with payments in excess of fair value being recorded as an intangible asset and a corresponding liability.

Taxation

Management estimation is required to determine the amount of deferred tax assets that can be recognised based upon likely timing and level of future taxable profits together with assessment of the effect of future tax planning strategies.

Impairment of investments in group undertakings

Where there are indicators of impairment of investments in group undertakings, the Company performs impairment tests based on fair value less costs to sell or a value in use calculation. The fair value less costs to sell calculation is based on available data from binding sales transactions in an arm’s length transaction on similar assets or observable market prices less incremental costs for disposing of the asset.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

c. Functional currency

Items included in these financial statements are measured using the currency of the primary economic environment in which the Company operates (the "functional currency"). The financial statements are presented in the United States Dollars ("$"), which is the Company's functional and presentation currency.

Transactions during the period denominated in foreign currencies have been translated at the rates of exchange ruling at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated to US$ at the rate of exchange ruling at the balance sheet date. The resulting profits or losses are dealt with in the profit and loss account.

d. Investment in group companies

Investments in subsidiaries are recognised at cost less impairment.

The Company assesses at each reporting date whether investments in group undertakings may be impaired. If any such indication exists the Company estimates the recoverable amount of investments. If it is not possible to estimate the recoverable amount of the individual investments, the Company estimates, the recoverable amount of the cash generating unit to which the investments belongs. The recoverable amount of an investment or cash-generating unit is the higher of its fair value less costs to sell and its value in use. If the recoverable amount is less than its carrying amount, the carrying amount of the investment is impaired and it is reduced to its recoverable amount through an impairment in the income statement unless the investment is carried at a revalued amount where the impairment loss of a revalued asset is a revaluation decrease.

An impairment loss recognised for investments in group undertakings is reversed in a subsequent period if and only if the reasons for the impairment loss have ceased to apply.

e. Dividends

Dividends on Ordinary shares are recognised as a liability in the period in which they are declared by the Company.

f. Financial instruments

The Company categorises its financial instruments as ‘basic’ or ‘non-basic’ financial instruments and sub-categorises these as financial assets, financial liabilities, and equity instruments in accordance with the criteria set out in FRS 102.

Where financial assets or liabilities are deemed to meet the definition of ‘basic’ financial instruments they are measured at amortised cost using the effective interest method.

Where an financial asset or liability is categorised as non-basic it is accounted for a fair value through profit and loss. The fair values of financial instruments are determined using appropriate valuation techniques. In the case of warrants, the fair value is estimated using the Black-Scholes option-pricing model. Inputs include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants.

Equity instruments are measured at fair value of the cash received or receivable, net of direct issuance costs.

The Company has various warrant instruments which are classified as financial liabilities or equity instruments, depending on the specific terms of the warrant agreement.

Cash at bank and in hand
Cash and cash equivalents in the Statement of Financial Position comprise cash at bank and in hand and short term deposits with an original maturity date of three months or less.

NOTES TO COMPANY BALANCE SHEET

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

f. Financial instruments (continued)

Short-term debtors and creditors
Debtors and creditors with no stated interest rate and receivable or payable within one year are recorded at transaction price. Any losses arising from impairment are recognised in the income statement in operating expenses.

g. Profit and loss account

In accordance with Section 304 of the Companies Act 2014 the Company is availing of the exemption from presenting the individual profit and loss account. The Company's loss for the period from January 1, 2016 to December 31, 2016 was $102,891 thousand (2015: $167,615 thousand).

h. Taxation

Deferred taxation is accounted for in respect of all timing differences at tax rates enacted or substantively enacted at the balance sheet date. Timing differences arise from the inclusion of items of income and expenditure in tax computations in periods different from those in which they are included in the financial statements. A deferred tax asset is only recognised when it is more likely than not the asset will be recoverable in the foreseeable future out of suitable taxable profits from which the underlying timing differences can be recovered.

i. Share based payments

The Company and its subsidiaries operate various share based payment plans. The Company issues Ordinary shares related to these employee equity share programs at various subsidiaries.

The share based payment expense associated with the share plans is recognised as an expense by the entity which receives services in exchange for the share based compensation. In these Company only accounts, the expense related to the options vested are recorded in other reserves and charged to the appropriate entity that receives services.

j. Business combinations

When the Company enters into a transaction which involves the purchase of trade assets and liabilities, management consider whether the transaction meets the definition of a business.

Where a business is acquired, the transaction is accounted for as a business combination by applying acquisition accounting.

Where an acquisition of a group of assets does not meet the definition of a business combination it is considered to be an asset acquisition. Management have developed and applied an appropriate accounting policy for asset acquisitions, which is to recognise the acquired assets at their relative fair values. Goodwill is not recognised and therefore any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Management believe that this results in relevant information being presented in a way that most faithfully represents the transaction.

Where contingent consideration is payable in respect of a business combination or an asset acquisition, this is recognised when it is paid or becomes payable by the Company.

k. Intangible assets

Intangible assets consist of the Keveyis product New Drug Application (“NDA”). The Product’s orphan drug exclusivity period is considered to be a proxy for its useful economic life. The intangible asset will be amortised on a straight line basis over the useful economic life of the asset. The amortisation period commences when an asset is ready for use, which generally occurs when regulatory approval to market a product is obtained. Intangible assets are reviewed for impairment if there is objective evidence that, as a result of one or more events that occurred after initial recognition, the estimated recoverable value of the asset has been reduced. The recoverable amount of an asset is the higher of its fair value less costs to sell and its value in use.

NOTES TO COMPANY BALANCE SHEET

2. HISTORY AND DESCRIPTION OF THE COMPANY (CONTINUED)

Strongbridge Biopharma plc (“Strongbridge” or “the Company”), was incorporated under the laws of Ireland on May 26, 2015 with registered number 562659 as a public limited company under the Companies Act 2014 and is domiciled in Ireland.

The Company is a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. The Company’s first commercial product is Keveyis® (dichlorphenamide), the first and only treatment approved by the U.S. Food and Drug Administration (“FDA”) for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis. Keveyis, for which the Company holds the U.S. marketing rights, has orphan drug exclusivity status in the United States through August 7, 2022. In addition to this neuromuscular disease product, the Company has two clinical-stage product candidates for rare endocrine diseases, Recorlev and levoketoconazole. Recorlev (levoketoconazole, and formerly called COR-003) is a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome. Veldoreotide (formerly called COR-005) is a next-generation somatostatin analog (SSA) being investigated for the treatment of acromegaly, with potential additional applications in Cushing's syndrome and neuroendocrine tumors. Both Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency (“EMA”).

On August 7, 2015, the Company initiated an exchange offer for the outstanding shares of Cortendo AB. Cortendo AB shares were quoted on NOTC-A list. However, on October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the initial U.S. public offering of 2,500,000 ordinary shares at a price to the public became effective commencing the listing and trading on the NASDAQ Global Select Market under the symbol "SBBP". As a result of the above, on October 20, 2015, trading ceased on the NOTC-A list.

The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of $0.15, for beneficial interests in ordinary shares of Strongbridge, with a par value of SEK 1, in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge. Accordingly, On September 8, 2015, Strongbridge effected a 1-for-11 reverse stock split of its ordinary shares. With effect from September 8, 2015, the 0.418% of Cortendo AB not owned by Strongbridge Biopharma plc, is accounted for as a non-controlling interest. In September 2016, we acquired the non-controlling interest in Cortendo AB, after which Cortendo AB became a wholly-owned subsidiary of Strongbridge Biopharma plc. Total consideration paid per share was $13.66 resulting in an aggregate payment of $1.4 million (note 4).

On December 22, 2016, the Company raised $35 million in aggregate proceeds in a private placement (the "2016 Private Placement"). According to the terms of the Securities Purchase Agreement, dated December 22, 2016, we issued and sold 14,000,000 ordinary shares at a purchase price of $2.50 per ordinary share, as well as warrants to purchase 7,000,000 ordinary shares (the "Investor Warrants"), to the investors (the "2016 Investors"). The Investor Warrants are exercisable at a price of $2.50 per share beginning on June 28, 2017 and expire in five years from June 28, 2017. In connection with the 2016 Private Placement, we entered into a registration rights agreement with the 2016 Investors, pursuant to which we agreed to file the registration statement, for the purpose of registering for resale (i) the ordinary shares purchased by the 2016 Investors in the 2016 Private Placement, (ii) the ordinary shares exercisable upon exercise of the Investor Warrants acquired by the 2016 Investors in the 2016 Private Placement, and (iii) any other ordinary shares held by a 2016 Investor that beneficially owned at least 1,000,000 ordinary shares following the closing of the 2016 Private Placement that qualified as "Registrable Securities" as defined therein (the "Existing Shares").

On December 28, 2016, the Strongbridge Biopharma plc group entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Horizon Technology Finance Corporation ("Horizon"). The Loan Agreement provided for a $40 million credit facility, of which $20 million was borrowed initially. Under the Loan Agreement, we have access to two additional tranches of $10 million each, which would be available to us subject to the achievement of certain specified milestones. The borrowings pursuant to the Loan Agreement mature after 48 months. The Loan Agreement provides for interest-only payments initially for the first 18 months of the loan followed by an amortization period of 30 months, provides for a final payment fee equal to 8% of the amount borrowed, and bears interest at a rate equal to the sum of 8.22% plus the greater of 0.53% or the 30-day US LIBOR rate.

NOTES TO COMPANY BALANCE SHEET

2. HISTORY AND DESCRIPTION OF THE COMPANY (CONTINUED)

The credit facility provides that if we satisfy certain milestones and borrow the final $10 million tranche, the interest-only period would be extended by an additional six months and the amortization period would be 24 months. We have granted a security interest in substantially all of our existing assets and assets acquired by us in the future, including intellectual property. The Loan Agreement contains facility and prepayment fees, and customary affirmative and negative covenants, and events of default.

On December 28, 2016, the Company and three subsidiary undertakings jointly entered into a $40million loan and security agreement with Oxford Finance LLC and Horizon Technology Finance Corporation to which all of the borrowers are joint and severally liable. At the year-end $20 million of the facility had been drawn down. The borrowings mature after 48 months. In respect of the facility, the Company has granted a security interest in substantially all of its existing assets and assets acquired by the Company in the future, including intellectual property.

Upon the execution of the Loan Agreement, by a subsidiary, the Company issued warrants to each of Oxford and Horizon (the "Lenders") to purchase an aggregate of 428,571 ordinary shares at an exercise price equal to $2.45 per share (the "Lender Warrants"). The Lender Warrants are immediately exercisable and expire after ten years. The Lender Warrants issued to the Lenders include a provision requiring us to file the registration statement to provide for the public resale of the ordinary shares to be issued upon exercise of the Lender Warrants.

In December 2016, the Company initiated our rare neuromusculare franchise by acquiring the U.S. marketing rights to KEVEYIS® (dichlorphenamide) from Taro Pharmaceuticals U.S.A., Inc., the U.S. subsidiary of Taro Pharmaceutical Industries Ltd. (Taro). KEVEYIS is the first and only therapy approved in the United States to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis (PPP), a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis.

Under the terms of the Asset Purchase Agreement, we paid Taro an upfront payment of $1 million in December 2016 and will pay an additional $7.5 million to Taro by March 22, 2017, as well as an aggregate of $7.5 million in potential milestones upon the achievement of certain product sales targets. Taro has agreed to continue to manufacture Keveyis for us under an exclusive supply agreement through the orphan exclusivity period. We are obligated to purchase certain annual minimum amounts of product totalling approximately $29 million over a six-year period from Taro. Refer to page 65 note 8 for further detail.

3. INTANGIBLE FIXED ASSETS

In December 2016, the Company acquired the U.S. marketing rights to Keveyis.

	2016 $'000	2015 $'000
Arising on acquisition of U.S. marketing rights to Keveyis	40,177	-

The acquisition consideration for the US marketing rights to Keveyis includes consideration paid, deferred consideration payable and an estimate of the fair value of the additional consideration arising from the supply agreement with Taro. Where contingent consideration is payable this will be recognised as an addition to the asset cost in the period in which it arises.

	2016 $'000	2015 $'000
Consideration paid on acquisition	1,000	-
Deferred consideration	7,500	-
Transaction costs on acquisition	2,392	-
	10,892	-
Assets and liabilities acquired:		
Acquired U.S. marketing rights to Keveyis	40,177	-
Supply agreement liability	(29,285)	-
	10,892	-

NOTES TO COMPANY BALANCE SHEET

3. INTANGIBLE FIXED ASSETS (CONTINUED)

Our finite lived intangible asset consist of acquired developed product rights obtained from the asset acquisition of Keveyis® (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. ("Taro"). Keveyis is approved in the U.S. to treat hyperkalemic, hypokalemic and related variants of primary periodic paralysis, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Keveyis has received orphan drug exclusivity status in the U.S through August 7, 2022. In connection with the Asset Purchase and Supply Agreement we entered into with Taro Pharmaceutical Industries Ltd, we have paid Taro an upfront payment in two installments of $1 million in December 2016 and $7.5 million in March 2017.

We have concluded that the supply price payable by us exceeds fair value and, therefore, have used a discounted cash flow method with a probability assumption to value the payments in excess of fair value at $29.3 million ($4.2 million short term debt and $25.1 million long term debt), for which we have recorded an intangible asset and corresponding liability. This liability will be amortized as we purchase inventory over the term of the agreement. In addition, we incurred transaction costs of $2.4 million resulting in the recording of an Intangible Asset of $40.2 million. This asset will be amortised on a straight-line basis over an 8 year period.

4. FINANCIAL FIXED ASSETS

As at December 31, 2016 and as December 31, 2015 the Company had one direct subsidiary, Cortendo AB.

	2016	2015
	$'000	$'000
Balance as at beginning of year/period	142,418	308,639
Share based payments during the year/period	1,911	618
Purchase of non-controlling interest	1,413	-
Warrants relating to debt	882	-
Impairment at year/period end	(88,522)	(166,839)
Balance as at December 31, 2016	58,102	142,418

In order to effect a corporate reorganization, on September 8, 2015 we settled an exchange offer, which we refer to as the Exchange Offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis and non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc.

Following the settlement of the Exchange Offer, Strongbridge Biopharma plc became the parent of Cortendo AB and its subsidiaries.

With affect from September 8, 2015, the 0.418% of Cortendo AB not owned by Strongbridge Biopharma plc, is accounted for as a non-controlling interest. In September 2016, we acquired the non-controlling interest in Cortendo AB, after which Cortendo AB became a wholly-owned subsidiary of Strongbridge Biopharma plc.

Impairment of financial fixed assets

The Financial Fixed Asset initially recorded on the Company's balance sheet of approximately $308.6 million reflected a $16.50 per share value placed on the shares issued upon the closing of the exchange offer. On December 31, 2016, the closing share price was $2.40 (2015 $7.60), resulting in the market value of the Company's assets being considerably lower than the carrying value of the financial fixed assets at that date. Accordingly, the Company recorded an impairment charge in the profit and loss account of $90.4 million (2015: $166.8 million).

5. CASH AND CASH EQUIVALENTS

Cash at bank and in hand includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturity of three months or less. The total amount of cash and cash equivalents held at 31 December 2016 in thousands was $42,339 (2015:$21,782).

The Company changed banks during the year from Bank of America to Silicon Valley Bank. At December 31, 2016 Silicon Valley Bank had a credit rating of Aa3 (Moody's Investor Services Limited). At 31 December 2015, Bank of America had a credit rating of A1 (Moody's Investor Services Limited).

6. DEBTORS

Prepaid expenses and other current assets as at 31 December 2016 and 2015 can be summarised as follows:

	2016	2015
	$'000	$'000
Amounts due from subsidiary undertakings	6,784	-
Prepaid insurance	236	245
Other prepayments	69	15
VAT receivable	30	-
Total	7,119	260

7. CREDITORS – AMOUNTS DUE WITHIN ONE YEAR

Creditors (amounts due within one year) as at 31 December 2016 and 2015 can be summarised as follows:

	2016	2015
	$'000	$'000
Amounts due to subsidiary undertaking	14,648	3,040
Arising on acquisition of U.S. marketing rights to Keveyis	7,500	-
Supply agreement liability in relation to Keveyis	4,207	-
Professional fees	35	173
Accrued director fees	83	78
Tax liability	20	-
Other	271	8
Total	26,764	3,299

8. CREDITORS – AMOUNTS FALLING DUE AFTER MORE THAN ONE YEAR

Creditors (amounts falling due after more than one year) as at 31 December 2016 and 2015 can be summarised as follows:

	2016	2015
	$'000	$'000
Warrant liability in relation to equity	11,090	-
Supply agreement liability in relation to Keyevis	25,078	-
Total	36,168	-

Refer to note 3 above for further information regarding supply agreement liability in relation to Keyevis.

NOTES TO COMPANY BALANCE SHEET

9. SHARE CAPITAL

Ordinary shares

Voting rights and privileges

As at December 31, 2016 and as at December 31, 2015, the authorised share capital of the Company was €40,000 and $7,000,000 divided into 40,000 deferred ordinary shares of €1.00 each, 600,000,000 ordinary shares of $0.01 each, par value and 100,000,000 preferred shares of $0.01 each, par value.

As at December 31, 2016 and as at December 31, 2015, there were 40,000 deferred ordinary shares of €1.00 each. As at December 31, 2016 there were 35,335,026 ordinary shares of $0.01 each outstanding (2015: 21,205,382).

All amounts in respect to the allotted share capital have been called up and fully paid at the balance sheet date.

The holders of ordinary shares are entitled to one vote for each ordinary share held at all general meetings of shareholders without limitation. The holders are entitled to receive dividends if and when declared by the Board of Directors or by the Company in general meeting, provided no dividend shall exceed the amount recommended by the Board of Directors. No dividends have been declared or paid since inception. The holders are entitled to share rateably in the assets available for distribution to shareholders, in the event of any voluntary or involuntary liquidation.

The deferred ordinary shares are issued in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The deferred ordinary shares carry no voting rights and are not entitled to any dividend or distribution.

The authorised share capital for the Company can be summarised as follows:

	Deferred ordinary shares with par value of €1.00 each No of shares	Ordinary shares with par value of $0.01 each No of shares	Preferred shares with par value of $0.01 each No of shares
Incorporated on May 26, 2015 with authorised share capital of 1,000,000 ordinary shares of €1.00 each	1,000,000		
On August 7, 2015 reduction of 960,000 ordinary shares of €1.00 each	(960,000)		
On August 7, 2015 authorisation of 600,000,000 ordinary shares of $0.01 each		600,000,000	
On August 7, 2015 authorisation of 100,000,000 preferred shares of $0.01 each			100,000,000
Balance as at December 31, 2016 and 2015	40,000	600,000,000	100,000,000

In May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc), was incorporated under the laws of Ireland and issued 40,000 ordinary shares issued, par value €1.00. These shares were subsequently re-designated as deferred ordinary shares.

On August 7, 2015, the authorised share capital of the Company was amended by the reduction of 960,000 ordinary shares with a par value of €1.00 per share.

On August 7, 2015 authorised share capital was increased by 600,000,000 ordinary shares of $0.01 each and 100,000,000 preferred shares of $0.01 each.

NOTES TO COMPANY BALANCE SHEET

9. SHARE CAPITAL (CONTINUED)

The issued share capital for the Company can be summarised as follows:

	Deferred ordinary shares with par value of €1.00 each No of shares	Ordinary shares with par value of $0.01 each No of shares	Issued Share Capital at par €1.00/$0.01 $'000
Balance as at January 1, 2016	40,000	21,205,382	256
On December 22, 2016 issuance of shares, par value $0.01	-	14,000,000	140
Exercise of stock options	-	129,644	1
Balance as at December 31, 2016	40,000	35,335,026	397

	Deferred ordinary shares with par value of €1.00 each No of shares	Ordinary shares with par value of $0.01 each No of shares	Issued Share Capital at par €1.00/$0.01 $'000
On May 26, 2015, 40,000 ordinary shares issued, par value €1.00	40,000		44
On September 8, 2015 allotment of 205,759,204 ordinary shared issued, par value $0.01		205,759,204	2,058
On September 8, 2015 reverse stock split of 1-11 on ordinary shares, par value $0.01		(187,053,822)	(1,871)
On October 22, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering		2,500,000	25
Balance as at December 31, 2015	40,000	21,205,382	256

NOTES TO COMPANY BALANCE SHEET

10. CAPITAL & RESERVES

The share premium, other reserves and retained earnings for the Company for the year/period ended December 31, 2016 and 2015 can be summarised as follows:

Year ended December 31, 2016	Share Premium	Other Reserves	Warrant Reserves	Retained Earnings
	$'000	$'000	$'000	$'000
Balance as at January 1, 2016	326,031	2,489	-	(167,615)
Stock-based payment expense for the year	-	4,606	-	-
On December 22, 2016 allotment of 14,000,000 ordinary shared issued, par value $0.01 and warrants	23,132	(2,345)	-	-
Exercise of stock options	119	-	-	-
On December 28, 2016 issuance of warrants related to loan agreement	-	-	882	-
Net loss for the year	-	-	-	(102,891)
Balance as at December 31, 2016	349,282	4,750	882	(270,506)

On December 22, 2016, the Company raised $32.7 million, net of transaction costs, in a private placement of ordinary shares and warrants. The Company issued and sold 14,000,000 ordinary shares of common stock at a purchase price of $2.50 per ordinary share, par value $0.01, as well as warrants to purchase 7,000,000 shares. The warrants are exercisable at a price of $2.50 per share and expire in five years from the date of issuance.

Stock options of 129,644 ordinary shares were exercised during the year at a price of $2.30 per share, par value $0.01. Consideration for shares exercised was $120,000.

In relation to the private placement of ordinary shares and warrants referred to above, the terms of the warrants state, in the event of a sale of the Company, the terms of the warrants issued to the 2016 Investors in the 2016 Private Placement require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrant agreements). Therefore we are required to account for these warrants as liabilities and record at fair value at each reporting period. Fair value for these warrants was initially determined upon issuance using the Black-Scholes Model and were revalued at fair value as of December 31, 2016. The resulting decrease in fair value resulted in an unrealized gain of $0.6 million. As of December 31, 2016, the fair value of these warrants of $11.1 million was recorded as a long-term liability on our consolidated balance sheet.

NOTES TO COMPANY BALANCE SHEET

10. CAPITAL & RESERVES (CONTINUED)

Upon the execution of the Loan Agreement, by a subsidiary, the Company issued warrants to each of Oxford and Horizon (the "Lenders") to purchase an aggregate of 428,571 ordinary shares at an exercise price equal to $2.45 per share (the "Lender Warrants"). The Lender Warrants are immediately exercisable and expire after ten years. The Lender Warrants issued to the Lenders include a provision requiring us to file the registration statement to provide for the public resale of the ordinary shares to be issued upon exercise of the Lender Warrants.

Period ended December 31, 2015	Share Premium	Other Reserves	Retained Earnings
	$'000	$'000	$'000
On May 26, 2015, 40,000 deferred ordinary shares issued, par value €1.00	-	-	-
On September 8, 2015 allotment of 205,759,204 ordinary shared issued, par value $0.01	306,581	-	-
On September 8, 2015 reverse stock split of 1-11 on ordinary shares, par value $0.01	-	1,871	-
On October 16, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering	19,450	-	-
Share based payment	-	618	-
Net loss for the period	-	-	(167,615)
Balance as at December 31, 2015	326,031	2,489	(167,615)

Other reserves include $1,871,000 in relation to Capital Redemption Reserves and $618,000 in relation to Share Based Payment Reserves at 31 December 2015.

Share premium account

This reserve records the amount above the nominal value received for shares sold, less transaction costs.

Other reserves

This reserve is used to recognise the value of equity-settled share-based payments provided to employees of the group as part of their remuneration.

11. SHARE BASED PAYMENTS

Share based payment charges of $4,606 thousand (2015:$618 thousand) has been included in Other Reserves, $2,695 thousand (2015: nil) expensed during the year and $1,911 thousand (2015: $618 thousand) in Financial Fixed Assets. See notes to the Consolidated Financial Statements for full details on share based payment arrangements.

12. RELATED PARTY TRANSACTIONS

The Profit and Loss account includes $301,786 (2015: $78,312) of directors' fees for the year ended 31 December 2016 being the full amount of directors’ remuneration in the year. Share based payments to directors for year ended 31 December 2016 are $2,694,941 (2015: nil).

There were no contracts of any significance in relation to the business of the Company in which the directors had any interest, as defined in the Companies Act, 2014, at any time during the year or at the end of the financial year.

In accordance with section 33 paragraph 1A of FRS 102, disclosures need not be given of transactions entered into between two or more members of a group, provided that any subsidiary which is a party to the transaction is wholly owned by such a member. The Company has availed of this exemption.

NOTES TO COMPANY BALANCE SHEET

13. AUDITOR'S REMUNERATION

The fees paid to Ernst & Young Ireland are summarised below:

	As at December 31, 2016	As at December 31, 2015
Fees payable to the auditor	**$'000**	**$'000**
Audit of individual accounts	126	63
Tax advisory services	11	-
Other assurance services	-	117
Non-audit services	-	-
Total	137	180

The notes to the Consolidated Financial Statements provide additional information regarding auditor remuneration.

14. TAXATION

The company has incurred tax losses in the year that are available indefinitely for offset against future taxable profits. A deferred tax asset has not been recognised in respect to these losses as it is not probable that they will be recovered against future taxable profits.

15. SUBSEQUENT EVENTS

On March 31, 2017 we entered into an amendment to the Loan Agreement that was made effective as of January 27, 2017 and provided for an extension to the dates by which the Company's Swedish subsidiary was required to enter into security documents granting security interests on certain of its assets in favor of Oxford, as collateral agent for the Lender, and to increase the amount of debt the Company can incur under, and the amount of cash collateral it can provide for purposes of, its corporate credit card program from $100,000 to $250,000. In connection with the amendment, the Company paid $150,000 to the Lenders.

There were no other significant subsequent events from the end of the year until the date of signing of this report that would require an adjustment to or disclosure in the financial statements.

16. APPROVAL OF THE FINANCIAL STATEMENTS

The Financial Statements were approved and authorised for issue by the Board of Directors on 11 April 2017.